



# DECLARATION OF CONFORMITY TO DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

**Name of product** Alviguide™ Blue+ Interventional Cardiology Guiding Catheter

**Legal (labelled)** Alvimedica Tıbbi Ürünler Sanayi ve Dış Ticaret A.Ş.

**Manufacturer** İstanbul Trakya Serbest Bölgesi, Ferhatpaşa SB Mahallesi Atatürk Bulvarı No:16 34540  
Çatalca-İstanbul / TÜRKİYE

## Declaration

We, the undersigned, hereby declare that the medical device specified in this declaration conforms to the provisions of the *current* European Council (EC) Directive 93/42/EEC of June 14, 1993 concerning Medical Devices and therefore bears the CE mark of conformity on its labelling in combination with the Notified Body Identification number **0344 of DEKRA Certification B.V., Arnhem, The Netherlands.**

- Conformity to the applicable Essential Requirements for Safety and Performance per *current* Directive 93/42/EEC, Annex I: "Essential Requirements" has been proven,
- The device classification (i.e. **Class III**) has been determined per *current* Directive 93/42/EEC, Annex IX: Classification Criteria,
- The appropriate Conformity Assessment module per article 11 of the *current* Directive 93/42/EEC (i.e. **Annex II, Section 4**) has been followed as indicated on the "EC Design Examination" Certificate (**2161507DE04**) in combination with this Declaration of Conformity,
- Alvimedica's Quality Management System fulfils the Quality Management System requirements described in the *current* Directive 93/42/EEC (**Annex II, excluding Section 4**) and **EN ISO 13485:2016** as evidenced by the "CE Marking of Conformity" Certificate (**2161507CE02**), its accompanying Certification Notice and the Certificate of Registration (**2161507**). The specified medical device falls within the scope of Alvimedica's Quality Management System as indicated in the Certificates.

**GMDN** GMDN Term: **Vascular guide catheter, single-use**

GMDN Code: **17846**

**Valid** This Declaration of Conformity is valid until the expiration date indicated on the CE Marking of Conformity Certificate, i.e. the validity date indicated on the "CE Marking of Conformity" Certificate issued by DEKRA to Alvimedica.

**Reference** RA-DOC-002 Rev. 021 – Annex to the Declaration of Conformity.

**Place of issue** İstanbul, Turkey

**Declared by:** Didem Kantar  
Quality Assurance Manager

**Date:** 2021-05-31



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## Annex to the Declaration of Conformity - Supporting Information –

Supporting Information to the “Declaration of Conformity to Directive 93/42/EEC  
concerning Medical Devices”

for

**Alviguide™ Blue+ Interventional Cardiology Guiding Catheter (RA-DOC-002  
Rev.021)**

<b>Legal (labeled)</b>	Alvimedica Tıbbi Ürünler Sanayi ve Dış. Ticaret A.Ş.
<b>Manufacturer</b>	İstanbul Trakya Serbest Bölgesi, Ferhatpaşa SB Mahallesi Atatürk Bulvarı No:16 34540 Çatalca-İstanbul / TÜRKİYE
<b>Supporting documentation</b>	Documentation that contains proof of compliance to the aforementioned Directive is described below and is retained under the premises of the manufacturer.

### I. Technical Information

- The Regulatory File (Summary of Technical Documentation / STED) **Alviguide Blue+** demonstrates compliance with the relevant essential requirements of the current Directive 93/42/EEC.
- To certify that the type of the product falling within the indicated product category conforms to the provisions of the Directive 93/42/EEC in accordance with **Annex II, excluding Section 4** of the Directive, DEKRA issued to Alvimedica a “CE Marking of Conformity” Certificate (**2161507CE02**) for the guiding catheter (initially issued on **May 23, 2013**).
- To certify that the type of the products falling within the indicated product category conforms to the provisions of the *current* Directive 93/42/EEC in accordance with **Annex II (Section 4)** of the Directive, DEKRA issued to Alvimedica an “EC Design Examination” Certificate (**2161507DE04**) per *current* Directive 93/42/EEC **Annex II**.
- The Declaration of Conformity for this Guiding catheter (**Class III**) is valid in combination with the current CE Marking of Conformity Certificate.
- This DOC is valid until the expiration date indicated on the CE Marking of Conformity Certificate.

This Declaration of Conformity covers:

Product Category (collective term)	Tracking system and associated devices
Generic Device Group term	Intravascular guiding catheter
Product type (family)	Alviguide™ Blue+ Interventional Cardiology Guiding Catheter

### II. Quality Management Systems

The below certificate has been issued by the indicated Notified Bodies to Alvimedica in respect of the operations (development, manufacturing and distribution) at the indicated site and for the products mentioned in the scope of the registration.

- Certificate of Registration issued by DEKRA to Alvimedica to certify that the Quality Management System complies with the relevant requirement of **EN ISO 13485:2016 (2161507)** for the activities detailed in the scope of the registration.



# DECLARATION OF CONFORMITY TO DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

## Supportive Information

<b>Authorized Representative European Community</b>	ALVIMEDICA MEDICAL TECHNOLOGIES FRANCE Immeuble Neos 14 avenue de L'Europe 77144 Montevrain France
<b>Notified Body</b>	The Notified Body that assesses the conformity of Alvimedica's products and Alvimedica's Quality Management System with the requirements of the Directive 93/42/EEC is: DEKRA Certification b.v. Meander 1051 6825 MJ Arnhem Telephone +31 (0) 889683000 Site: <a href="http://www.dekra-certification.nl">www.dekra-certification.nl</a> Notified Body I.D. no: 0344

## Characteristics

Regulatory File:	Guiding Catheters
Name Product / Device Type:	<b>Alviguide™ Blue+ Interventional Cardiology Guiding Catheter</b>
Legal Manufacturer:	Alvimedica Tibbi Ürünler Sanayi ve Dış Ticaret A.Ş. İstanbul Trakya Serbest Bölgesi, Ferhatpaşa SB Mahallesi Atatürk Bulvarı No:16 34540 Çatalca-İstanbul / TÜRKİYE
Manufacturing location: (Final assembly)	
Distribution:	
Sterilisation location:	
Indication for Use:	
Classification:	See Attachment 1.
Catalogue (REF) numbers:	
List of shapes:	
Lot numbers:	See Attachment 2.
Device Category and Subcategory (Collective Term) & Generic Device Group (Global Medical Device Nomenclature (GMDN):	
Applied International Standards:	See Attachment 3.
Shelf Life (Use By Date)	36 months

## Statements

### Alvimedica's Alviguide™ Blue+ Interventional Cardiology Guiding Catheters:

- do **not** incorporate, as an integral part, a medicinal product.
- do **not** contain tissue of biological origin, i.e., do **not** contain tissue of animal origin or (human) blood derivatives.
- are sterile with Sterility Assurance Level (SAL)  $10^{-6}$  (SAL =  $10E-6$ ).
- are sterilized using Ethylene oxide (EtO) sterilization.
- are **non-pyrogenic**.
- product & manufacturing processes are **latex-free**.
- product & manufacturing processes do **not** contain phthalates.

**Place of issue:** İstanbul, Turkey

**Approved by:** Didem Kantar, Quality Assurance Manager

**Date:** 2021-05-31



# DECLARATION OF CONFORMITY TO DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

## Attachment 1: Device Names, Indication for Use, Classification, Catalogue and Lot Numbers

**Device Name / Type:** Alviguides™ Blue+ Interventional Cardiology Guiding Catheter

**Indication for Use:** Alviguides™ Blue+ Interventional Cardiology Guiding Catheter is intended for use in the intravascular introduction of interventional/diagnostic devices into the coronary vascular systems.

**Class:** Based on classification **Rule 6** of Annex IX of the Directive 93/42/EEC concerning Medical Devices, the device is considered a **Class III** device.

### CATALOGUE NUMBER

Current Reference Code	Size	Product Definition	Manufactured Date
503110202301	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 3.0 5F	10/22/2014
503110202302	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 3.5 5F	8/21/2013
503110202303	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 4.0 5F	6/28/2013
503110202304	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 4.5 5F	3/28/2014
503110202305	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 5.0 5F	9/26/2014
503110202306	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 6.0 5F	9/8/2014
503110202307	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 3.0 PP 5F	
503110202308	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 3.5 PP 5F	10/22/2013
503110202309	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 4.0 PP 5F	7/24/2013
503110202310	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 4.5 PP 5F	10/10/2017
503110202311	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 5.0 PP 5F	
503110202312	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GCJUDKINS LEFT 6.0 PP 5F	
503110202313	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT MOD. 4.0 MOD 5F	
503110202314	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT MOD. 4.0 MOD PP 5F	
503110202315	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GCJUDKINS LEFT 3.5 ST5F	12/17/2014
503110202316	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GCJUDKINS LEFT 4.0 ST5F	12/17/2014
503110202317	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GCJUDKINS LEFT 4.5 ST5F	
503110202318	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GCJUDKINS LEFT 5.0 ST5F	
503110202319	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 3.5 STPP 5F	12/20/2014
503110202320	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 4.0 STPP 5F	12/20/2014
503110202371	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.0 ST PP 5F	12/20/2014
503110202372	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.5 ST PP 5F	
503110202373	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 2.0 ST PP 5F	





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Current Reference Code	Size	Product Definition	Manufactured Date
503110202374	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 3.0 ST PP 5F	
503110202375	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ RIGHT 1.0 5F	9/12/2013
503110202376	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ RIGHT 2.0 5F	9/12/2013
503110202377	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ RIGHT 3.0 5F	9/12/2013
503110202378	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ RIGHT 1.0 PP 5F	12/20/2014
503110202379	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ RIGHT 2.0 PP 5F	
503110202380	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ RIGHT 3.0 PP 5F	10/24/2013
503110202381	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT RIGHT 1.25F	8/24/2017
503110202382	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT RIGHT 1.2 PP 5F	
503110202383	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC LEFT EXTRA SUPPORT 3.0 5F	9/17/2013
503110202384	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC LEFT EXTRA SUPPORT 3.5 5F	9/16/2013
503110202385	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC LEFT EXTRA SUPPORT 4.0 5F	9/9/2013
503110202386	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC LEFT EXTRA SUPPORT 4.5 5F	11/16/2014
503110202387	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC LEFT EXTRA SUPPORT 3.0 PP 5F	5/27/2014
503110202388	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC LEFT EXTRA SUPPORT 3.5 PP 5F	10/25/2013
503110202389	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC LEFT EXTRA SUPPORT 4.0 PP 5F	10/27/2013
503110202390	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC LEFT EXTRA SUPPORT 4.5 PP 5F	3/17/2016
503110202321	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 4.5 PP 5F	
503110202322	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 5.0 PP 5F	
503110202323	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT CURVED 3.5 5F	5/25/2016
503110202324	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT CURVED 4.0 5F	5/25/2016
503110202325	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT CURVED 4.5 5F	
503110202326	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT CURVED 5.0 5F	
503110202327	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT CURVED 3.5 PP 5F	
503110202328	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT CURVED 4.0 PP 5F	
503110202329	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT CURVED 4.5 PP 5F	
503110202330	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT CURVED 5.0 PP 5F	
503110202331	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 3.5 5F	8/21/2013



## DECLARATION OF CONFORMITY TO DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

Current Reference Code	Size	Product Definition	Manufactured Date
503110202332	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 4.0 5F	6/28/2013
503110202333	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 4.5 5F	1/6/2014
503110202334	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 5.0 5F	1/6/2014
503110202335	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 6.0 5F	12/30/2014
503110202336	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 3.5 PP 5F	4/26/2014
503110202337	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 4.0 PP 5F	10/22/2013
503110202338	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT JR 4.5 PP 5F	10/21/2017
503110202339	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 5.0 PP 5F	
503110202340	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 6.0 PP 5F	
503110202341	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT3.5 ST 5F	12/17/2014
503110202342	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 4.0 ST 5F	12/17/2014
503110202343	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 4.5 ST 5F	
503110202344	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 5.0 ST 5F	
503110202345	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 3.5 ST PP 5F	12/20/2014
503110202391	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC RIGHT EXTRA SUPPORT 3.5 5F	3/28/2014
503110202392	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC RIGHT EXTRA SUPPORT 4.0 5F	3/28/2014
503110202393	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC RIGHT EXTRA SUPPORT 4.5 5F	12/18/2014
503110202394	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC RIGHT EXTRA SUPPORT 5.0 5F	
503110202395	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC RIGHT EXTRA SUPPORT 3.5 PP 5F	4/25/2014
503110202396	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC RIGHT EXTRA SUPPORT 4.0 PP 5F	
503110202397	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC RIGHT EXTRA SUPPORT 4.5 PP 5F	
503110202398	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC RIGHT EXTRA SUPPORT 5.0 PP 5F	
503110202399	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC CORONARY BYPASS LEFT 5F	4/22/2014
503110202401	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC CORONARY BYPASS LEFT PP 5F	
503110202402	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC CORONARY BYPASS RIGHT 5F	
503110202403	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC CORONARY BYPASSPP 5F	
503110202404	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC INTERNAL MAMMARY 5F	1/11/2014
503110202405	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC INTERNAL MAMMARY PP 5F	4/25/2014
503110202406	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC MULTIPURPOSE A1 5F	12/4/2013



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Current Reference Code	Size	Product Definition	Manufactured Date
503110202407	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC MULTIPURPOSE A1 PP 5F	12/17/2014
503110202408	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC MULTIPURPOSE B1 5F	8/22/2017
503110202409	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC MULTIPURPOSE B1 PP 5F	
503110202410	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC HOCKEY STICK 5F	12/11/2014
503110202411	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC HOCKEY STICK PP 5F	1/11/2014
503110202412	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC EL GAMAL 5F	12/11/2014
503110202413	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC EL GAMAL PP 5F	
503110202414	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC SONES CURVES SON 1 5F	
503110202415	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC SONES CURVES SON 2 5F	
503110202416	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC SONES CURVES SON 3 5F	
503110202346	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 4.0 ST PP 5F	12/19/2014
503110202347	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 4.5 ST PP 5F	
503110202348	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 5.0 ST PP 5F	
503110202349	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT CURVED 3.5 5F	
503110202350	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT CURVED 4.0 5F	4/12/2018
503110202351	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT CURVED 4.5 5F	
503110202352	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT CURVED 3.5 PP 5F	
503110202353	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT CURVED 4.0 PP 5F	
503110202354	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT CURVED 4.5 PP 5F	
503110202355	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT .75 5F	5/14/2014
503110202356	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.0 5F	9/9/2013
503110202357	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.2 5F	10/22/2014
503110202358	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.5 5F	5/25/2016
503110202359	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 2.0 5F	9/9/2013
503110202360	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 3.0 5F	9/9/2013
503110202361	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT .75 PP 5F	
503110202362	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.0 PP 5F	10/22/2013
503110202363	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.2 PP 5F	
503110202364	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.5 PP 5F	





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Current Reference Code	Size	Product Definition	Manufactured Date
503110202365	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 2.0 PP 5F	10/22/2013
503110202366	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 3.0 PP 5F	10/21/2013
503110202367	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.0 ST 5F	10/20/2013
503110202368	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.5 ST 5F	
503110202369	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 2.0 ST 5F	
503110202370	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 3.0 ST 5F	
503110202417	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC SONES CURVES SON 1 PP 5F	
503110202418	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC SONES CURVES SON 2 PP 5F	
503110202419	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC SONES CURVES SON 3 PP 5F	
503110202420	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC CASTILLO CURVES CAST 1 5F	
503110202421	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC CASTILLO CURVES CAST 2 5F	
503110202422	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC CASTILLO CURVES CAST 3 5F	
503110202423	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC CASTILLO CURVES CAST 1 PP 5F	
503110202424	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC CASTILLO CURVES CAST 2 PP 5F	
503110202425	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC CASTILLO CURVES CAST 3 PP 5F	
503110202426	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC ATEŞAL 3.5, 5F	
503110202427	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC ATEŞAL 4.0, 5F	
503110202428	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC ATEŞAL 4.5, 5F	
503110202429	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC ATEŞAL 3.5 PP, 5F	
503110202430	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC ATEŞAL 4.0 PP, 5F	
503110202431	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC ATEŞAL 4.5 PP, 5F	
503110202432	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC PR, PROGRESSIVE RIGHT, 5F	
503110202433	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC PR, PROGRESSIVE RIGHT PP, 5F	
503110202438	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC Q 4, 5F	9/11/2017
503110202439	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC Q 4 PP, 5F	
503110202440	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC MOD. EXTRA BACK UP, Mod. 5F	2/28/2014
503110202441	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC MOD. EXTRA BACK UP, Mod. PP, 5F	
503110202446	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC COR. BYPASS GRAFT RIGHT 5F	





## DECLARATION OF CONFORMITY TO DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

Current Reference Code	Size	Product Definition	Manufactured Date
503110202447	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC COR. BYPASS GRAFT LEFT, 5F	
503110202448	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC COR. BYPASS GRAFT RIGHT PP, 5F	
503110202449	5F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC COR. BYPASS GRAFT LEFT PP, 5F	
503110202601	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 3.0 6F	10/20/2013
503110202602	6F	ALVIGUIDE BLUE + INTERVENTIONAL ARDIOLOGY GC JUDKINS LEFT 3.5 6F	6/28/2013
503110202603	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 4.0 6F	6/11/2013
503110202604	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 4.5 6F	5/29/2013
503110202605	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 5.0 6F	6/28/2013
503110202606	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 6.0 6F	10/3/2013
503110202607	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 3.0 PP 6F	2/15/2016
503110202608	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 3.5 PP 6F	6/28/2013
503110202609	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 4.0 PP 6F	6/28/2013
503110202610	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 4.5 PP 6F	8/21/2013
503110202611	6F	ALVIGUIDE BLUE + INTERVENTIONAL ARDIOLOGY GC JUDKINS LEFT 5.0 PP 6F	10/11/2013
503110202612	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 6.0 PP 6F	10/10/2013
503110202613	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT MOD. 4.0 6F	
503110202614	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT MOD. 4.0 PP 6F	
503110202615	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 3.5 ST 6F	6/28/2013
503110202616	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 4.0 ST 6F	6/28/2013
503110202617	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 4.5 ST 6F	
503110202618	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 5.0 ST 6F	
503110202619	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 3.5 ST PP 6F	12/22/2014
503110202620	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 4.0 ST PP 6F	6/28/2013
503110202621	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 4.5 ST PP 6F	
503110202622	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 5.0 ST PP 6F	
503110202623	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT CURVED 3.5 6F	3/28/2014
503110202624	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT CURVED 4.0 6F	3/28/2014
503110202625	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT CURVED 4.5 6F	3/18/2016
503110202671	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.0 ST PP 6F	12/22/2014



## DECLARATION OF CONFORMITY TO DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

Current Reference Code	Size	Product Definition	Manufactured Date
503110202672	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.5 ST PP 6F	
503110202673	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 2.0 ST PP 6F	
503110202674	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 3.0 ST PP 6F	
503110202675	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ RIGHT 1.0 6F	6/28/2013
503110202z76	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ RIGHT 2.0 6F	8/24/2013
50311020277	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ RIGHT 3.0 6F	10/3/2013
503110202678	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ RIGHT 1.0 PP 6F	10/19/2013
503110202679	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ RIGHT 2.0 PP 6F	8/26/2013
503110202680	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ RIGHT 3.0 PP 6F	
503110202681	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT RIGHT 1.2 6F	11/17/2014
503110202682	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT RIGHT 1.2 PP 6F	10/4/2013
503110202683	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC LEFT EXTRA SUPPORT 3.0 6F	6/28/2013
503110202684	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC LEFT EXTRA SUPPORT 3.5 6F	6/28/2013
503110202685	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC LEFT EXTRA SUPPORT 4.0 6F	11/14/2013
503110z02686	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC LEFT EXTRA SUPPORT 4.5 6F	5/17/2014
503110202687	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC LEFT EXTRA SUPPORT 3.0 PP 6F	7/25/2013
503110202688	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC LEFT EXTRA SUPPORT 3.5 PP 6F	7/26/2013
50311020269	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC LEFT EXTRA SUPPORT 4.0 PP 6F	11/14/2013
503110202690	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC LEFT EXTRA SUPPORT 4.5 PP 6F	10/4/2013
503110202691	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC RIGHT EXTRA SUPPORT 3.5 6F	10/20/2013
503110202692	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC RIGHT EXTRA SUPPORT 4.0 6F	8/14/2013
503110202693	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC RIGHT EXTRA SUPPORT 4.5 6F	10/20/2013
503110202694	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC RIGHT EXTRA SUPPORT 5.0 6F	10/23/2013
503110202695	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC RIGHT EXTRA SUPPORT 3.5 PP 6F	10/23/2013
503110202626	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT CURVED 5.0 6F	
503110202627	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT CURVED 3.5 PP 6F	3/28/2014
503110202628	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT CURVED 4.0 PP 6F	3/28/2014
503110202629	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT CURVED 4.5 PP 6F	4/13/2018
503110202630	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT CURVED 5.0 PP 6F	4/12/2018



## DECLARATION OF CONFORMITY TO DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

Current Reference Code	Size	Product Definition	Manufactured Date
503110202631	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 3.5 6F	6/28/2013
503110202632	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 4.0 6F	6/28/2013
503110202633	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 4.5 6F	1/6/2014
503110202634	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 5.0 6F	9/13/2013
503110202635	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 6.0 6F	9/8/2014
503110202636	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 3.5 PP 6F	6/28/2013
503110202637	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 4.0 PP 6F	6/28/2013
503110202638	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 4.5 PP 6F	10/21/2017
503110202639	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 5.0 PP 6F	11/8/2013
503110202640	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 6.0 PP 6F	4/12/2018
503110202641	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 3.5 ST 6F	12/21/2014
503110202642	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 4.0 ST 6F	8/18/2014
503110202643	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 4.5 ST 6F	
503110202644	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 5.0 ST 6F	
503110202645	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 3.5 ST PP 6F	12/21/2014
503110202646	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 4.0 ST PP 6F	8/19/2014
503110202647	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 4.5 ST PP 6F	
503110202648	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 5.0 ST PP 6F	
503110202649	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT CURVED 3.5 6F	6/19/2017
503110202650	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT CURVED	11/16/2014
503110202696	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC RIGHT EXTRA SUPPORT 4.0 PP 6F	8/14/2013
503110202697	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC RIGHT EXTRA SUPPORT 4.5 PP 6F	10/24/2013
503110202698	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC RIGHT EXTRA SUPPORT 5.0 PP 6F	11/22/2013
503110202699	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC COR. BYPASS LEFT 6F	10/4/2013
503110202701	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC COR. BYPASS LEFT PP 6F	8/26/2014
503110202702	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC COR. BYPASS RIGHT 6F	10/4/2013
503110202703	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC COR. BYPASS RIGHT PP 6F	8/26/2014
503110202704	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC INTERNAL MAMMARY 6F	7/24/2013
503110202705	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC INTERNAL MAMMARY PP 6F	8/14/2013





## DECLARATION OF CONFORMITY TO DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

Current Reference Code	Size	Product Definition	Manufactured Date
503110202706	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC MULTIPURPOSE A1 6F	10/4/2013
503110202707	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC MULTIPURPOSE A1 PP 6F	10/23/2013
503110202708	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC MULTIPURPOSE B1 6F	10/20/2013
503110202709	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC MULTIPURPOSE B1 PP 6F	10/23/2013
503110202710	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC HOCKEY STICK 6F	8/21/2013
503110202711	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC HOCKEY STICK PP 6F	8/21/2013
503110202712	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC EL GAMAL 6F	10/23/2013
503110202713	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC EL GAMAL PP 6F	10/23/2013
503110202714	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC SONES CURVES SON 1 6F	10/23/2013
503110202715	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC SONES CURVES SON 2 6F	10/23/2013
503110202716	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC SONES CURVES SON 3 6F	10/23/2013
503110202717	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC SONES CURVES SON 1 PP 6F	10/23/2013
503110202718	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC SONES CURVES SON 2 PP 6F	10/23/2013
503110202719	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC SONES CURVES SON 3 PP 6F	10/23/2013
503110202720	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC CASTILLO CURVES CAST 1, 6F	10/23/2013
503110202721	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC CASTILLO CURVES CAST 2, 6F	10/23/2013
503110202651	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT CURVED 4.5 6F	6/25/2019
503110202652	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT CURVED 3.5 PP 6F	
503110202653	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT CURVED 4.0 PP 6F	
503110202654	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT CURVED 4.5 PP 6F	
503110202655	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT .75 6F	1/6/2014
503110202656	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.0 6F	8/14/2013
503110202657	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.2 6F	1/16/2014
503110202658	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.5 6F	2/8/2014
503110202659	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 2.0 6F	8/14/2013
503110202660	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 3.0 6F	8/21/2013
503110202661	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT .75 PP 6F	5/24/2014
503110202662	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.0 PP 6F	8/14/2013
503110202663	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.2 PP 6F	12/10/2018





## DECLARATION OF CONFORMITY TO DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

Current Reference Code	Size	Product Definition	Manufactured Date
503110202664	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.5 PP 6F	3/17/2016
503110202665	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 2.0 PP 6F	8/14/2013
503110202666	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 3.0 PP 6F	11/8/2013
503110202667	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.0 ST 6F	7/13/2014
503110202668	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.5 ST 6F	
503110202669	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 2.0 ST 6F	6/4/2014
503110202670	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 3.0 ST 6F	11/18/2014
503110202901	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 3.0 7F	10/20/2013
503110202902	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 3.5 7F	6/28/2013
503110202903	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 4.0 7F	6/28/2013
503110202904	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 4.5 7F	10/4/2013
503110202905	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 5.0 7F	10/4/2013
503110202906	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 6.0 7F	10/4/2013
503110202722	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC CASTILLO CURVES CAST 3, 6F	10/23/2013
503110202723	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC CASTILLO CURVES CAST 1 PP, 6F	10/23/2013
503110202724	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC CASTILLO CURVES CAST 2 PP 6F	10/23/2013
503110202725	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC CASTILLO CURVES CAST 3 PP, 6F	10/24/2013
503110202726	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC ATEŞAL 3.5, 6F	
503110202727	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC ATEŞAL 4.0, 6F	
503110202728	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC ATEŞAL 4.5, 6F	
503110202729	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC ATEŞAL 3.5 PP, 6F	
503110202730	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC ATEŞAL 4.0 PP, 6F	
503110202731	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC ATEŞAL 4.5 PP, 6F	
503110202732	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC PR, PROGRESSIVE RIGHT, 6F	10/24/2013
503110202733	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC PR, PROGRESSIVE RIGHT PP,6F	10/24/2013
503110202738	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC Q 4, 6F	10/23/2013
503110202739	6F	ALVIGUIDE BLUE + INTERVENTIONALCARDIOLOGY GC Q 4 PP, 6F	10/23/2013
503110202740	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC MOD. EXTRA BACK UP, Mod., 6F	8/29/2013
503110202741	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC MOD. EXTRA BACK UP, Mod. PP, 6F	8/29/2013



## DECLARATION OF CONFORMITY TO DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

Current Reference Code	Size	Product Definition	Manufactured Date
503110202746	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC COR. BYPASS GRAFT RIGHT, 6F	10/26/2013
503110202747	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC COR. BYPASS GRAFT LEFT, 6F	10/20/2013
503110202748	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC COR. BYPASS GRAFT RIGHT PP, 6F	10/23/2013
503110202749	6F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC COR. BYPASS GRAFT LEFT PP, 6F	10/24/2013
503110202971	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.0 ST PP 7F	12/15/2014
503110202972	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.5 ST PP 7F	
503110202973	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 2.0 ST PP 7F	
503110202974	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 3.0 ST PP 7F	
503110202975	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ RIGHT 1.0 7F	10/26/2013
503110202976	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ RIGHT 2.0 7F	10/26/2013
503110202907	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 3.0 PP 7F	2/3/2016
503110202908	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 3.5 PP 7F	10/4/2013
503110202909	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 4.0 PP 7F	6/28/2013
503110202910	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 4.5 PP 7F	10/4/2013
503110202911	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 5.0 PP 7F	6/28/2013
503110202912	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 6.0 PP 7F	10/4/2013
503110202913	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT MOD. 4.0 MOD 7F	
503110202914	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT MOD. 4.0PP 7F	
503110202915	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 3.5 ST 7F	12/15/2014
503110202916	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 4.0 ST 7F	12/11/2014
503110202917	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 4.5 ST 7F	
503110202918	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 5.0 ST 7F	
503110202919	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 3.5 ST PP 7F	12/15/2014
503110202920	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 4.0 ST PP 7F	12/17/2014
503110202921	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 4.5 ST PP 7F	3/11/2014
503110202922	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 5.0 ST PP 7F	
503110202923	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT CURVED 3.5 7F	
503110202924	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT CURVED 4.0 7F	
503110202925	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT CURVED 4.57F	



## DECLARATION OF CONFORMITY TO DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

Current Reference Code	Size	Product Definition	Manufactured Date
503110202926	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT CURVED 5.0 7F	
503110202927	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT CURVED 3.5 PP 7F	
503110202928	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT CURVED 4.0 PP 7F	
503110z02977	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ RIGHT 3.0 7F	10/24/2013
503110202978	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ RIGHT 1.0 PP 7F	10/27/2013
503110202979	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ RIGHT 2.0 PP 7F	3/25/2014
503110202980	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ RIGHT 3.0 PP 7F	
503110202981	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT RIGHT 1.2 7F	
503110202982	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT RIGHT 1.2 PP 7F	
503110202983	7F	ALVIGUIDE BLUE + INTERVENTIONA L CARDIOLOGY GC LEFT EXTRA SUPPORT 3.0 7F	10/23/2013
503110202984	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC LEFT EXTRA SUPPORT 3.5 7F	10/7/2013
503110202985	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC LEFT EXTRA SUPPORT 4.0 7F	7/26/2013
503110202986	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC LEFT EXTRA SUPPORT 4.5 7F	10/23/2013
503110202987	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC LEFT EXTRA SUPPORT 3.0 PP 7F	10/23/2013
503110202988	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC LEFT EXTRA SUPPORT 3.5 PP 7F	10/19/2013
503110202989	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC LEFT EXTRA SUPPORT 4.0 PP 7F	8/14/2013
503110202990	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC LEFT EXTRA SUPPORT 4.5 PP 7F	10/23/2013
503110202991	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC RIGHT EXTRA SUPPORT 3.5 7F	9/14/2013
503110202992	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC RIGHT EXTRA SUPPORT 4.0 7F	8/26/2013
503110202993	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC RIGHT EXTRA SUPPORT 4.5 7F	10/7/2013
503110202994	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC RIGHT EXTRA SUPPORT 5.0 7F	
503110202995	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC RIGHT EXTRA SUPPORT 3.5 PP 7F	10/7/2013
503110202996	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC RIGHT EXTRA SUPPORT 4.0 PP 7F	8/26/2013
503110202997	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC RIGHT EXTRA SUPPORT 4.5 PP 7F	
503110202998	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC RIGHT EXTRA SUPPORT 5.0 PP 7F	
503110202929	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT CURVED 4.5 PP 7F	
503110202930	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT CURVED 5.0 PP 7F	
503110202931	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 3.5 7F	11/9/2013
503110202932	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 4.0 7F	6/28/2013





## DECLARATION OF CONFORMITY TO DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

Current Reference Code	Size	Product Definition	Manufactured Date
503110202933	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 4.5 7F	12/10/2014
503110202934	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 5.0 7F	11/11/2013
503110202935	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 6.0 7F	10/23/2013
503110202936	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 3.5 PP 7F	10/7/2013
503110202937	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 4.0 PP 7F	6/28/2013
503110202938	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 4.5 PP 7F	
503110202939	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 5.0 PP 7F	10/4/2013
503110202940	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 6.0 PP 7F	
503110202941	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 3.5 ST 7F	12/11/2014
503110202942	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 4.0 ST 7F	12/11/2014
503110202943	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 4.5 ST 7F	
503110202944	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT J 5.0 ST 7F	9/9/2014
503110202945	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 3.5 ST PP 7F	12/14/2014
503110202946	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 4.0 ST PP 7F	12/14/2014
503110202947	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 4.5 ST PP 7F	
503110202948	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 5.0 ST PP 7F	
503110202949	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT CURVED 3.5 7F	
503110202950	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT CURVED 4.0 7F	
503110202951	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT CURVED 4.5 7F	
503110202952	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT CURVED 3.5 PP 7F	
503110202953	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT CURVED 4.0 PP 7F	
503110202954	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT CURVED 4.5 PP 7F	
503110202955	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT .75 7F	2/9/2019
503110202999	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC COR. BYPASS LEFT 7F	8/25/2014
503110203001	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC COR. BYPASS LEFT PP 7F	8/27/2014
503110203002	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC COR. BYPASS RIGHT 7F	8/25/2014
503110203003	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC COR. BYPASS RIGHT PP 7F	8/27/2014
503110203004	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC INTERNAL MAMMARY 7F	8/14/2013
503110203005	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC INTERNAL MAMMARY PP 7F	8/14/2013





## DECLARATION OF CONFORMITY TO DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

Current Reference Code	Size	Product Definition	Manufactured Date
503110203006	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC MULTIPURPOSE A1 7F	12/4/2013
503110203007	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC MULTIPURPOSE A1 PP 7F	3/20/2014
503110203008	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC MULTIPURPOSE B1 7F	3/11/2014
503110203009	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC MULTIPURPOSE B1 PP 7F	8/25/2014
503110203010	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC HOCKEY STICK 7F	8/15/2014
503110203011	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC HOCKEY STICK PP 7F	3/25/2014
503110203012	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC EL GAMAL 7F	12/11/2014
503110203013	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC EL GAMAL PP 7F	
503110203014	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC SONES CURVES SON 1 7F	
503110203015	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC SONES CURVES SON 2 7F	11/16/2014
503110203016	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC SONES CURVES SON 3 7F	
503110203017	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC SONES CURVES SON 1 PP 7F	
503110203018	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC SONES CURVES SON 2 PP 7F	
503110203019	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC SONES CURVES SON 3 PP 7F	
503110203020	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC CASTILLO CURVES CAST 1 7F	
503110203021	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC CASTILLO CURVES CAST 2 7F	
503110203022	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC CASTILLO CURVES CAST 3 7F	
503110203023	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GCCASTILLO CURVES CAST 1 PP 7F	
503110203024	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GCCASTILLO CURVES CAST 2 PP 7F	
503110203025	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GCCASTILLO CURVES CAST 3 PP 7F	
503110203026	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC ATEŞAL 3.5, 7F	
503110202956	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.0 7F	10/20/2013
503110202957	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.2 7F	
503110202958	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.5 7F	10/20/2013
503110202959	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 2.0 7F	10/20/2013
503110202960	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 3.0 7F	10/20/2013
503110202961	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT .75 PP 7F	
503110202962	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.0 PP 7F	9/24/2013
503110202963	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.2 PP 7F	



## DECLARATION OF CONFORMITY TO DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

Current Reference Code	Size	Product Definition	Manufactured Date
503110202964	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.5 PP 7F	3/11/2014
503110202965	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 2.0 PP 7F	3/20/2014
503110202966	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 3.0 PP 7F	8/25/2014
503110202967	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.0 ST 7F	12/15/2014
503110202968	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.5 ST 7F	3/11/2014
503110202969	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 2.0 ST 7F	
503110202970	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 3.0 ST 7F	
503110203201	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 3.0 8F	10/20/2013
503110203202	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 3.5 8F	12/19/2013
503110203203	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 4.0 8F	10/11/2013
503110203204	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 4.5 8F	
503110203205	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 5.0 8F	10/23/2013
503110203206	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 6.0 8F	10/20/2013
503110203207	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 3.0 PP 8F	
503110203208	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 3.5 PP 8F	
503110203209	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 4.0 PP 8F	10/19/2013
503110203210	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 4.5 PP 8F	10/20/2013
503110203211	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 5.0 PP 8F	
503110203212	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 6.0 PP 8F	
503110203027	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC ATEŞAL 4.0, 7F	
503110203028	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC ATEŞAL 4.5, 7F	
503110203029	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC ATEŞAL 3.5 PP, 7F	
503110203030	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC ATEŞAL 4.0 PP, 7F	
503110203031	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC ATEŞAL 4.5 PP, 7F	
503110203032	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC PR, PROGRESSIVE RIGHT, 7F	3/11/2014
503110203033	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC PR, PROGRESSIVE RIGHT PP 7F	
503110203038	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC Q 4, 7F	3/11/2014
503110203039	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC Q 4 PP, 7F	
503110203040	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC MOD. EXTRA BACK UP, Mod.7F	10/7/2013



## DECLARATION OF CONFORMITY TO DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

Current Reference Code	Size	Product Definition	Manufactured Date
503110203041	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC MOD. EXTRA BACK UP, Mod. PP 7F	10/7/2013
503110203046	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC COR. BYPASS GRAFT RIGHT 7F	
503110203047	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC COR. BYPASS GRAFT LEFT 7F	
503110203048	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC COR. BYPASS GRAFT RIGHT PP, 7F	3/11/2014
503110203049	7F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC COR. BYPASS GRAFT LEFT PP, 7F	1/21/2015
503110203271	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.0 ST PP 8F	
503110203272	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.5 ST PP 8F	
503110203273	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 2.0 ST PP 8F	
503110203274	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 3.0 ST PP 8F	
503110203275	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ RIGHT 1.0 8F	10/20/2013
503110203276	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ RIGHT 2.0 8F	10/20/2013
503110203277	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ RIGHT 3.0 8F	10/20/2013
503110203278	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ RIGHT 1.0 PP 8F	
503110203279	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ RIGHT 2.0 PP 8F	
503110203280	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ RIGHT 3.0 PP 8F	
503110203281	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT RIGHT 1.2 8F	
503110203282	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT RIGHT 1.2 PP 8F	
503110203213	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT MOD. 4.0 MOD 8F	
503110203214	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT MOD. 4.0 MOD PP 8F	
503110203215	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 3.5 ST 8F	
503110203216	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 4.0 ST 8F	
503110203217	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 4.5 ST 8F	
503110203218	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 5.0 ST 8F	
503110203219	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 3.5 ST PP 8F	
503110203220	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 4.0 ST PP 8F	
503110203221	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 4.5 ST PP 8F	
503110203222	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT 5.0 ST PP 8F	
503110203223	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT CURVED 3.5 8F	
503110203224	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT CURVED 4.0 8F	





## DECLARATION OF CONFORMITY TO DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

Current Reference Code	Size	Product Definition	Manufactured Date
503110203225	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT CURVED 4.5 8F	
503110203226	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT CURVED 5.0 8F	9/8/2014
503110203227	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT CURVED 3.5 PP 8F	
503110203228	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT CURVED 4.0 PP 8F	
503110203229	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT CURVED 4.5 PP 8F	
503110203230	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS LEFT CURVED 5.0 PP 8F	
503110203231	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 3.5 8F	3/28/2014
503110203232	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 4.0 8F	9/24/2013
503110203233	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 4.5 8F	3/28/2014
503110203234	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 5.0 8F	
503110203283	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC LEFT EXTRA SUPPORT 3.0 8F	10/21/2013
503110203284	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC LEFT EXTRA SUPPORT 3.5 8F	10/21/2013
503110203285	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC LEFT EXTRA SUPPORT 4.0 8F	9/24/2013
503110203286	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC LEFT EXTRA SUPPORT 4.5 8F	10/21/2013
503110203287	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC LEFT EXTRA SUPPORT 3.0 PP 8F	10/22/2013
503110203288	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC LEFT EXTRA SUPPORT 3.5 PP 8F	10/22/2013
503110203289	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC LEFT EXTRA SUPPORT 4.0 PP 8F	10/22/2013
503110203290	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC LEFT EXTRA SUPPORT 4.5 PP 8F	10/22/2013
503110203291	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC RIGHT EXTRA SUPPORT 3.5 8F	
503110203292	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC RIGHT EXTRA SUPPORT 4.0 8F	
503110203293	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC RIGHT EXTRA SUPPORT 4.5 8F	
503110203294	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC RIGHT EXTRA SUPPORT 5.0 8F	
503110203295	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC RIGHT EXTRA SUPPORT 3.5 PP 8F	
503110203296	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC RIGHT EXTRA SUPPORT 4.0 PP 8F	10/10/2014
503110203297	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC RIGHT EXTRA SUPPORT 4.5 PP 8F	
503110203298	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC RIGHT EXTRA SUPPORT 5.0 PP 8F	
503110203299	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC CORONARY BYPASS LEFT 8F	
503110203301	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC CORONARY BYPASS LEFT PP 8F	
503110203302	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC CORONARY BYPASS RIGHT 8F	





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Current Reference Code	Size	Product Definition	Manufactured Date
503110203303	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC CORONARY BYPASS RIGHT PP 8F	
503110203304	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC INTERNAL MAMMARY 8F	2/5/2019
503110203305	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC INTERNAL MAMMARY PP 8F	
503110203235	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 6.0 8F	
503110203236	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 3.5 PP 8F	
503110203237	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 4.0 PP 8F	10/25/2013
503110203238	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 4.5 PP 8F	
503110203239	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 5.0 PP 8F	
503110203240	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 6.0 PP 8F	
503110203241	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 3.5 ST 8F	
503110203242	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 4.0 ST 8F	
503110203243	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 4.5 ST 8F	
503110203244	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 5.0 ST 8F	
503110203245	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 3.5 ST PP 8F	
503110203246	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 4.0 ST PP 8F	
503110203247	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 4.5 ST PP 8F	
503110203248	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT 5.0 ST PP 8F	
503110203249	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT CURVED 3.5 8F	
503110203250	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT CURVED 4.0 8F	
503110203251	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT CURVED 4.5 8F	8/29/2014
503110203252	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT CURVED 3.5 PP 8F	
503110203253	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT CURVED 4.0 PP 8F	
503110203254	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC JUDKINS RIGHT CURVED 4.5 PP 8F	
503110203255	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT .75 8F	
503110203256	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.0 8F	10/20/2013
503110203257	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.2 8F	
503110203258	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.5 8F	10/20/2013
503110203259	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 2.0 8F	10/20/2013
503110203260	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 3.0 8F	10/20/2013



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Current Reference Code	Size	Product Definition	Manufactured Date
503110203261	8F	ALVIGUIDE BLUE + INTERVENTIONAL ARDIOLOGY GC AMPLATZ LEFT .75 PP 8F	
503110203306	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC MULTIPURPOSE A1 8F	6/26/2014
503110203307	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC MULTIPURPOSE A1 PP 8F	
503110203308	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC MULTIPURPOSE B1 8F	
503110203309	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC MULTIPURPOSE B1 PP 8F	
503110203310	8F	ALVIGUIDE BLUE + INTERVENTIONALCARDIOLOGY GC HOCKEY STICK 8F	
503110203311	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC HOCKEY STICK PP 8F	
503110203312	8F	ALVIGUIDE BLUE + INTERVENTIONALCARDIOLOGY GC EL GAMAL 8F	
503110203313	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC EL GAMAL PP 8F	
503110203314	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC SONES CURVES SON 1 8F	
503110203315	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC SONES CURVES SON 2 8F	
503110203316	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC SONES CURVES SON 3 8F	
503110203317	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC SONES CURVES SON 1 PP 8F	
503110203318	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC SONES CURVES SON 2 PP 8F	
503110203319	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC SONES CURVES SON 3 PP 8F	
503110203320	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC CASTILLO CURVES CAST 1 8F	
503110203321	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC CASTILLO CURVES CAST 2 8F	
503110203322	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC CASTILLO CURVES CAST 3 8F	
503110203323	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC CASTILLO CURVES CAST 1 PP8F	
503110203324	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC CASTILLO CURVES CAST 2 PP 8F	
503110203325	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC CASTILLO CURVES CAST 3 PP8F	
503110203326	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC ATEŞAL 3.5, 8F	
503110203327	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC ATEŞAL 4.0, 8F	
503110203328	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC ATEŞAL 4.5, 8F	
503110203329	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC ATEŞAL 3.5 PP, 8F	
503110203330	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC ATEŞAL 4.0 PP, 8F	
503110203331	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC ATEŞAL 4.5 PP, 8F	
503110203332	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC PR, PROGRESSIVE RIGHT, 8F	
503110203262	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.0 PP 8F	10/15/2014



## DECLARATION OF CONFORMITY TO DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

Current Reference Code	Size	Product Definition	Manufactured Date
503110203263	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.2 PP 8F	
503110203264	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.5 PP 8F	
503110203265	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 2.0 PP 8F	10/15/2014
503110203266	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 3.0 PP 8F	
503110203267	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.0 ST 8F	8/29/2014
503110203268	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 1.5 ST 8F	
503110203269	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 2.0 ST 8F	
503110203270	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC AMPLATZ LEFT 3.0 ST 8F	
503110203333	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC PR, PROGRESSIVE RIGHT PP,8F	
503110203338	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC Q 4, 8F	
503110203339	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC Q 4 PP, 8F	
503110203340	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC MOD. EXTRA BACK UP, Mod. 8F	
503110203341	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC MOD. EXTRA BACK UP, Mod. PP, 8F	
503110203346	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC COR. BYPASS GRAFT RIGHT, 8F	
503110203347	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY CARDIOLOGY GC COR. BYPASS GRAFT LEFT, 8F	
503110203348	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC COR. BYPASS GRAFT RIGHT PP, 8F	
503110203349	8F	ALVIGUIDE BLUE + INTERVENTIONAL CARDIOLOGY GC COR. BYPASS GRAFT LEFT PP, 8F	

**Lot Number(s)** This Declaration of Conformity applies to lot numbers manufactured as of June 1, 2013 and coded: **5-yy-mm-dd sequential 3 digits derived from SAP; starting with 5130601xxx.**



## DECLARATION OF CONFORMITY TO DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

### Attachment 2: Device Category and Subcategory (Collective Term), Generic Device Group (Global Medical Device Nomenclature (GMDN))

#### Global Medical Device Nomenclature -GMDN- Classification

Device Category (per GMDN database):	
Codes:	Terms:
10	<b>Single use devices</b>
Device Subcategory - Collective Terms (CT's per GMDN database):	
Codes:	Terms:
CT 346	Cardiology
CT 145	Cardiovascular devices
CT 123	Angioplasty systems and associated devices
CT 335	Single purpose
CT 334	Single-patient use
CT 233	Surgical
CT 339	Transcutaneous/Percutaneous
CT 983	Surgical Invasive
CT 320	Transient surgical invasive
CT 979	Inorganic materials
CT 201	Synthetic polymers
CT 179	Plastics
CT 212	Silicone
CT 336	Sterile
CT 130	Catheters and associated devices
CT1581	Catheters
CT 477	Cardiovascular catheters
CT 432	Guides/Guidewires and associated devices
CT 2315	Tracking system and associated devices
Generic Device Group (preferred term per GMDN database)	
Preferred Term:	<b>Vascular guide catheter, single-use</b>
GMDN Code:	<b>17846</b>
<p>Definition: A flexible tube with a central lumen used for the percutaneous, transluminal passage and placement of guidewires and diagnostic/interventional devices within the vascular system. After the tube is inserted in position, a guidewire is advanced through its lumen and tracked over by a diagnostic/interventional device (e.g., balloon dilatation catheter, stent and delivery system, or embolization device) to the intended location. The distal section of the tube can have a variety of preformed shapes (e.g., straight, multi-purpose, hockey stick, renal double curve); it typically has radiopaque markers so that it can be fluoroscopically tracked. This is a single-use device.</p>	





# DECLARATION OF CONFORMITY TO DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

## Attachment 3: Declarations of Conformity to applied (recognized) International Standards

ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-4 V2:2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017)
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
EN ISO 10993-6:2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:2016)
EN ISO 10993-7:2008/Amd1:2019	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals - Amendment 1: Applicability of allowable limits for neonates and infants (ISO 10993-7:2008/Amd.1:2019)
EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2013)
EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
EN ISO 10993-12:2012	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2012)
ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process
EN ISO 11135:2014/A1:2019	Sterilization of health care products - Ethylene oxide Requirements for development, validation and routine control of a sterilization process for medical devices Amendment 1: Revision of Annex E, Single batch release (ISO 11135:2014/Amd 1:2018)
EN ISO 11737-1:2018	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)
EN ISO 11737-2:2019	Sterilization of health care products- Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2009)
ISO 11607-1:2019	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006, including Amd 1:2014)
ISO 11607-2:2019	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2006, including Amd 1:2014)
EN 868-2:2017	Packaging for terminally sterilized medical devices - Part 2: Sterilization wrap - Requirements and test methods
EN 868-4:2017	Packaging for terminally sterilized medical devices - Part 4: Paper bags - Requirements and test methods
EN 868-5:2018	Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods
EN 868-6:2017	Packaging for terminally sterilized medical devices - Part 6: Paper for low temperature sterilization processes - Requirements and test methods
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2016-12-15)
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 11070:2014	Sterile single-use intravascular introducers, dilators and guidewires (ISO 11070:2014)
EN ISO 14644-1:2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015)
EN ISO 14644-2: 2015	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015)
EN ISO 13485:2016/AC:2018	Medical devices. Quality management systems - Requirements for



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MDD-93-42-EEC	regulatory purposes (ISO 13485:2016) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
EN ISO 14971:2019	Medical devices- Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
EN 556-1:2001/AC:2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" – Part 1: Requirements for terminally sterilized medical devices
ASTM D5276 - 17	Standard Test Method for Drop Test of Loaded Containers by Free Fall
ASTM F1980 - 16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM F 1929-15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
EN ISO 10555-1:2013/ A1:2017	Intravascular catheters – Sterile and single-use catheters - Part 1: General requirements – Amendment 1 (ISO 10555-1:2013/ Amd 1:2017)
EN ISO 14155:2020	Clinical investigation of medical devices for human subjects – Good clinical practice
EN ISO 80369-7:2017	Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications (ISO 80369-7:2016, Corrected version 2016-12-01)
EN ISO/IEC 17050-1:2010	Conformity assessment - Supplier's declaration of conformity - Part 1: General requirements (EN ISO/IEC 17050-1:2004, corrected version 2007-06-15)
EN ISO/IEC 17050-2:2004	Conformity assessment - Supplier's declaration of conformity - Part 2: Supporting documentation (ISO/IEC 17050-2:2004)
EN ISO 11138-1:2017	Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2017)
EN ISO 11138-2:2017	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2017)
EN ISO 14937:2009	Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices (ISO 14937:2009)
ISO/TS 11139:2018	Sterilization of health care products - Vocabulary
EN ISO 14161:2009	Sterilization of health care products - Biological indicators - Guidance for the selection, use and interpretation of results (ISO 14161:2009)
MEDDEV 2.7/1 Rev.4	Clinical Evaluation a Guide for Manufacturers and Notified Bodies Under Directives
MEDDEV 2.12/1 Rev.8	Guidelines on A Medical Devices Vigilance System
MEDDEV 2.5/5 Rev.3	Translation Procedure