



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

pName of product Alvision™ Interventional Cardiology Diagnostic 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 (**2161507DE03**) 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: **Angiographic catheter, single-use**

GMDN Code: **10688**

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-003 Rev. 022 – 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

Alvision™ Interventional Cardiology Diagnostic Catheter (RA-DOC-003 Rev.022)

Legal (labeled) 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
Supporting documentation 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) **Alvision** 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 diagnostic 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 (**2161507DE03**) per *current* Directive 93/42/EEC **Annex II**.
- The Declaration of Conformity for this diagnostic 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)	Vascular infusion/aspiration catheters
Generic Device Group term	Angiographic catheter, single-use
Product type (family)	Alvision™ Interventional Cardiology Diagnostic 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.



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Supportive Information

Authorized Representative European Community	ALVIMEDICA MEDICAL TECHNOLOGIES FRANCE Immeuble Neos 14 avenue de L'Europe 77144 Montevrain France
Notified Body	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: www.dekra-certification.nl Notified Body I.D. no: 0344

Characteristics

Regulatory File:	Angiographic Catheters
Name Product / Device Type:	Alvision™ Interventional Cardiology Diagnostic Catheter
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:	
Device Category and Subcategory (Collective Term) & Generic Device Group (Global Medical Device Nomenclature (GMDN):	See Attachment 2.
Applied International Standards:	See Attachment 3.
Shelf Life (Use By Date)	36 months

Statements

Alvimedica's **Alvision™ Interventional Cardiology Diagnostic 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: Istanbul, Turkey

Approved by: Didem Kantar, Quality Assurance Manager

Date: 2021-05-31



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

Device Name / Type: Alvision™ Interventional Cardiology Diagnostic Catheter

Indication for Use: Alvision™ Interventional Cardiology Diagnostic Catheters are intended for use in the delivery of radio-opaque media to selected sites in the vascular system.

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.

ALVISION INTERVENTIONAL CARDIOLOGY DC 5 PACK CONFIGURATION

Current Reference Code	Size	Product Definition	Curve Type and Length	Manufactured Date
501110019601	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 3.0 – 100 cm	5/31/2013
501110019602	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 3.5 – 100 cm	5/31/2013
501110019603	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.0 – 100 cm	5/31/2013
501110019604	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.0 SHORT TIP – 100 cm	11/29/2014
501110019605	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.5 – 100 cm	5/31/2013
501110019606	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 5.0 – 100 cm	5/31/2013
501110019607	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 6.0 – 100 cm	5/31/2013
501110019608	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 3.0 – 100 cm	5/31/2013
501110019609	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 3.5 – 100 cm	5/31/2013
501110019610	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.0 – 100 cm	5/31/2013
501110019611	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.5 – 100 cm	5/31/2013
501110019612	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 5.0 – 100 cm	5/31/2013
501110019613	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 6.0 – 100 cm	5/31/2013
501110019614	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT I – 100 cm	7/18/2013
501110019615	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT II – 100 cm	10/7/2013
501110019631	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I - 80 cm	1/31/2018
501110019632	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II - 80 cm	
501110019633	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III - 80 cm	
501110019634	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I PP – 100 cm	
501110019635	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II PP – 100 cm	
501110019636	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III PP – 100 cm	
501110019637	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAİL STRAIGHT - 110 cm	8/28/2013
501110019638	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAİL 145 - 110 cm	6/19/2013
501110019639	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAİL 155 - 110 cm	2/17/2014



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Current Reference Code	Size	Product Definition	Curve Type and Length	Manufactured Date
501110019640	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 4.0 - 100 cm	12/10/2013
501110019641	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ALVISION ATEŞAL 3.5 - 100 cm	12/10/2013
501110019616	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT III - 100 cm	9/9/2013
501110019617	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT I - 100 cm	5/31/2013
501110019618	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT II - 100 cm	5/31/2013
501110019619	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT III - 100 cm	10/25/2013
501110019620	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT MODIFIED B - 100 cm	11/28/2014
501110019621	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS- LEFT- 100 cm	11/27/2014
501110019622	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS- RIGHT - 100 cm	11/27/2014
501110019623	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	INTERNAL MAMMARY - 100 cm	9/9/2013
501110019624	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE A-1 - 100 cm	6/19/2013
501110019625	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE A-2 - 100 cm	7/19/2013
501110019626	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE B-1 - 100 cm	6/24/2015
501110019627	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE B-2 - 100 cm	1/31/2014
501110019628	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I - 100 cm	4/29/2017
501110019629	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II - 100 cm	7/19/2018
501110019630	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III - 100 cm	
501110019652	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS GRAFT LEFT - 100 cm	11/28/2014
501110019701	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 3.0 - 100 cm	7/3/2013
501110019702	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 3.5 - 100 cm	6/18/2013
501110019703	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.0 SHORT TIP - 100 cm	7/26/2013
501110019704	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.0 - 100 cm	5/29/2013
501110019705	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.5 - 100 cm	7/14/2013
501110019706	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 5.0 - 100 cm	5/29/2013
501110019707	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 6.0 - 100 cm	6/19/2013
501110019708	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 3.0 - 100 cm	9/6/2013
501110019709	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 3.5 - 100 cm	10/27/2013
501110019710	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.5 - 100 cm	7/23/2013



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Current Reference Code	Size	Product Definition	Curve Type and Length	Manufactured Date
501110019642	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 4.5 -100cm	12/5/2014
501110019643	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	HOCKEY STICK -100cm	5/25/2015
501110019644	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PROGRESSIVE RIGHT - 100cm	
501110019647	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	Q4 -100cm	
501110019648	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MOD. EXTRA BACK UP -100cm	11/28/2014
501110019651	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS GRAFT RIGHT - 100cm	11/28/2014
501110019718	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT II - 100 cm	5/24/2013
501110019719	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT III - 100 cm	5/31/2013
501110019720	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT MODIFIED B - 100 cm	11/23/2014
501110019721	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS- LEFT - 100 cm	5/27/2013
501110019722	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS- RIGHT - 100 cm	5/24/2013
501110019723	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	INTERNAL MAMMARY - 100 cm	6/18/2013
501110019724	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE A-1 - 100 cm	10/28/2013
501110019725	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE A-2 - 100 cm	9/10/2013
501110019726	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE B-1 - 100 cm	7/15/2013
501110019727	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE B-2 - 100 cm	7/16/2013
501110019728	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I - 100 cm	6/19/2014
501110019729	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II - 100 cm	10/23/2014
501110019730	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III - 100 cm	11/13/2017
501110019731	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I - 80 cm	1/29/2019
501110019732	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II - 80 cm	1/29/2019
501110019733	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III - 80 cm	
501110019734	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I PP - 100 cm	
501110019735	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II PP - 100 cm	1/19/2016
501110019736	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III PP - 100 cm	6/25/2014
501110019737	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL STRAIGHT - 110 cm	7/18/2013
501110019738	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 145 - 110 cm	7/15/2013
501110019711	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.0 - 100 cm	6/19/2013



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Current Reference Code	Size	Product Definition	Curve Type and Length	Manufactured Date
501110019712	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 5.0 - 100 cm	6/19/2013
501110019714	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT I - 100 cm	5/24/2013
501110019715	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT II - 100 cm	5/24/2013
501110019716	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT III - 100 cm	5/31/2013
501110019717	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT I - 100 cm	5/24/2013
501110019802	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 3.5 - 100 cm	6/18/2013
501110019803	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.0 - 100 cm	6/12/2013
501110019804	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.0 SHORT TIP - 100 cm	7/26/2013
501110019805	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.5 - 100 cm	5/23/2013
501110019806	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 5.0 - 100 cm	11/4/2013
501110019807	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 6.0 - 100 cm	10/26/2013
501110019808	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 3.0 - 100 cm	7/25/2013
501110019809	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 3.5 - 100 cm	5/27/2013
501110019810	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.0 - 100 cm	6/7/2013
501110019811	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.5 - 100 cm	7/23/2013
501110019812	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 5.0 - 100 cm	8/22/2013
501110019813	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 6.0 - 100 cm	5/23/2013
501110019814	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT I - 100 cm	5/24/2013
501110019815	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT II - 100 cm	5/24/2013
501110019816	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT III - 100 cm	5/28/2013
501110019817	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT I - 100 cm	5/24/2013
501110019818	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT II - 100 cm	5/24/2013
501110019740	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 3.5 - 100 cm	8/20/2013
501110019741	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 4.0 - 100 cm	5/30/2013
501110019742	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 4.5 - 100 cm	11/19/2013
501110019743	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	HOCKEY STICK - 100 cm	11/22/2014
501110019739	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAİL 155 -110 cm	7/15/2013
501110019744	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PROGRESSIVE RIGHT-100 cm	10/31/2016



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Current Reference Code	Size	Product Definition	Curve Type and Length	Manufactured Date
501110019747	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	Q4-100 cm	10/26/2015
501110019748	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MOD. EXTRA BACK UP-100 cm	2/28/2014
501110019751	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS GRAFT RIGHT-100 cm	11/22/2014
501110019752	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS GRAFT LEFT-100 cm	11/23/2014
501110019801	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 3.0 - 100 cm	6/26/2013
501110019819	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT III - 100 cm	5/28/2013
501110019820	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT MODIFIED B - 100 cm	11/23/2014
501110019821	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS- LEFT - 100 cm	5/27/2013
501110019822	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS- RIGHT - 100 cm	5/27/2013
501110019823	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	INTERNAL MAMMARY - 100 cm	5/27/2013
501110019824	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE A-1 - 100 cm	7/15/2013
501110019825	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE A-2 - 100 cm	2/21/2014
501110019826	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE B-1- 100 cm	5/27/2013
501110019827	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE B-2- 100 cm	7/16/2013
501110019828	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I - 100 cm	12/2/2014
501110019829	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II - 100 cm	4/22/2014
501110019830	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III - 100 cm	4/22/2014
501110019831	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I -80 cm	
501110019832	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II -80 cm	
501110019833	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III -80 cm	
501110019834	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I PP - 100 cm	11/13/2017
501110019835	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II PP -100 cm	1/19/2016
501110019905	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.5 -100 cm	11/8/2013
501110019906	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 5.0 -100 cm	6/18/2013
501110019907	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 6.0 -100 cm	10/25/2013
501110019836	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III PP -100 cm -100 cm	
501110019837	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAİL STRAIGHT 110 cm	5/31/2013
501110019838	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAİL 145 - 110 cm	7/20/2013



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Current Reference Code	Size	Product Definition	Curve Type and Length	Manufactured Date
501110019839	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 155 - 110 cm	7/25/2013
501110019840	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 3.5-100 cm	8/20/2013
501110019841	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 4.0-100 cm	8/20/2013
501110019842	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 4.5-100 cm	11/19/2013
501110019843	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	HOCKEY STICK-100 cm	11/27/2013
501110019844	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PROGRESSIVE RIGHT-100 cm	7/18/2016
501110019847	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	Q4-100 cm	11/28/2013
501110019848	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MOD. EXTRA BACK UP-100 cm	11/27/2013
501110019851	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS GRAFT RIGHT-100 cm	10/27/2013
501110019852	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS GRAFT LEFT-100 cm	10/26/2013
501110019901	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 3.0 -100 cm	11/21/2014
501110019902	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 3.5 -100 cm	11/21/2014
501110019903	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.0 -100 cm	8/21/2013
501110019904	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.0 SHORT TIP -100 cm	11/21/2014
501110019922	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS- RIGHT – 100 cm	8/22/2013
501110019923	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	INTERNAL MAMMARY – 100 cm	11/21/2014
501110019924	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE A-1 – 100 cm	5/21/2015
501110019925	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE A-2 -100 cm	8/14/2013
501110019926	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE B-1 -100 cm	3/18/2016
501110019927	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE B-2 -100 cm	
501110019928	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I -100 cm	10/26/2015
501110019929	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II -100 cm	
501110019930	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III -100 cm	
501110019931	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I -80 cm	
501110019908	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 3.0 -100 cm	11/20/2014
501110019909	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 3.5 -100 cm	11/20/2014
501110019910	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.0 -100 cm	6/18/2013
501110019911	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.5 -100 cm	11/8/2013



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Current Reference Code	Size	Product Definition	Curve Type and Length	Manufactured Date
501110019912	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 5.0 -100 cm	6/14/2014
501110019913	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 6.0 -100 cm	10/25/2013
501110019914	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT I -100 cm	10/26/2013
501110019915	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT II -100 cm	10/25/2013
501110019932	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II -80 cm	
501110019933	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III -80 cm	
501110019934	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I PP -100 cm	
501110019935	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II PP -100 cm	1/19/2016
501110019936	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III PP -100 cm	
501110019937	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAİL STRAIGHT -110 cm	4/21/2014
501110019938	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAİL 145 -110 cm	1/12/2015
501110019947	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	Q4 -100 cm	
501110019916	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT III – 100 cm	3/17/2016
501110019917	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT I -100 cm	10/25/2013
501110019918	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT II -100 cm	10/26/2013
501110019919	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT III -100 cm	10/25/2013
501110019920	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT MODIFIED B -100 cm	11/24/2014
501110019921	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS- LEFT -100cm	8/22/2013
501110019948	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MOD. EXTRA BACK UP-100 cm	6/17/2014
501110019951	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS GRAFT RIGHT-100 cm	
501110019939	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAİL 155- 110 cm	1/12/2015
501110019940	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 4.0 -100 cm	1/10/2018
501110019941	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 3.5-100 cm	1/11/2018
501110019942	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 4.5-100 cm	
501110019943	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	HOCKEY STICK-100 cm	
501110019944	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PROGRESSIVE RIGHT -100 cm	
501110019952	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS GRAFT LEFT -100 cm	
501110019501	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 6.0 -125 cm	#N/A (New Size)



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Current Reference Code	Size	Product Definition	Curve Type and Length	Manufactured Date
501110019502	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.0 -125 cm	#N/A (New Size)
501110019503	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 5.0 -125 cm	#N/A (New Size)
501110019504	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.0 -125 cm	#N/A (New Size)
501110019505	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 5.0 -125 cm	#N/A (New Size)
501110019506	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 6.0 -125 cm	#N/A (New Size)
501110019507	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.0 -125 cm	#N/A (New Size)
501110019508	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 5.0 -125 cm	#N/A (New Size)
501110019509	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 6.0 -125 cm	#N/A (New Size)
501110019526	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL STRAIGHT -125 cm	#N/A (New Size)
501110019527	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL STRAIGHT -125 cm	#N/A (New Size)
501110019510	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.0 -125 cm	#N/A (New Size)
501110019511	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 5.0 -125 cm	#N/A (New Size)
501110019512	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 6.0 -125cm	#N/A (New Size)
501110019513	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.0 -125 cm	#N/A (New Size)
501110019514	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 5.0 -125 cm	#N/A (New Size)
501110019515	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 6.0 -125 cm	#N/A (New Size)
501110019516	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.0 -125 cm	#N/A (New Size)
501110019517	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 5.0 -125 cm	#N/A (New Size)
501110019518	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 6.0-125 cm	#N/A (New Size)
501110019519	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 145° -125 cm	#N/A (New Size)
501110019520	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 155° -125 cm	#N/A (New Size)
501110019521	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 145° -125 cm	#N/A (New Size)
501110019522	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 155° -125 cm	#N/A (New Size)
501110019523	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 145° -125 cm	#N/A (New Size)
501110019524	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 155° -125 cm	#N/A (New Size)
501110019525	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL STRAIGHT -125 cm	#N/A (New Size)



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ALVISION INTERVENTIONAL CARDIOLOGY DC 10 PACK CONFIGURATION

Current Reference Code	Size	Product Definition	Curve Type and Length	Manufacturer Date
501110188401	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 3.0 - 100 cm	
501110188402	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 3.5 - 100 cm	3/28/2019
501110188403	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.0 - 100 cm	7/3/2013
501110188404	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT SHORT TIP 4.0 - 100 cm	
501110188405	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.5 - 100 cm	
501110188406	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 5.0 - 100 cm	
501110188407	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 6.0 - 100 cm	
501110188408	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 3.0 - 100 cm	
501110188409	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 3.5 - 100 cm	
501110188410	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.0 - 100 cm	3/27/2019
501110188411	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.5 - 100 cm	
501110188412	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 5.0 - 100 cm	
501110188413	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 6.0 - 100 cm	
501110188414	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT I - 100 cm	
501110188415	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT II - 100 cm	1/30/2018
501110188416	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT III - 100 cm	
501110188417	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT I - 100 cm	
501110188432	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II - 100 cm	
501110188433	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III - 100 cm	
501110188434	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I PP - 100 cm	
501110188435	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II PP - 100 cm	
501110188436	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III PP - 100 cm	
501110188418	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT II - 100 cm	
501110188419	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT III - 100 cm	
501110188420	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT MODIFIED B - 100 cm	
501110188421	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS-LEFT - 100 cm	
501110188422	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS-RIGHT - 100 cm	
501110188423	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	INTERNAL MAMMARY - 100 cm	12/5/2013
501110188424	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE A - 100 cm	
501110188425	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE A PP - 100 cm	
501110188426	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE B - 100 cm	
501110188427	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE B PP - 100 cm	
501110188428	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I - 100 cm	
501110188429	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II - 100 cm	
501110188430	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III - 100 cm	
501110188431	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I - 80 cm	
501110188432	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II - 80 cm	



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501110188433	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III - 80 cm	
501110188431	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I - 100 cm	
501110188520	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT MODIFIED B - 100 cm	
501110188521	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS-LEFT- 100 cm	12/20/2013
501110188522	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS-RIGHT - 100 cm	12/5/2013
501110188523	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	INTERNAL MAMMARY - 100 cm	12/5/2013
501110188524	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE A - 100 cm	1/10/2014
501110188437	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL STRAIGHT - 100 cm	10/4/2018
501110188438	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 145 - 100 cm	7/23/2013
501110188439	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 155 - 100 cm	
501110188440	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 3.5 - 100 cm	
501110188441	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 4.0 - 100 cm	
501110188442	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 4.5 - 100 cm	
501110188443	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	HOCKEY STICK - 100 cm	
501110188444	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PROGRESSIVE RIGHT - 100 cm	
501110188447	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	Q4 - 100 cm	
501110188448	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MOD. EXTRA BACK UP - 100 cm	
501110188451	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS GRAFT RIGHT - 100 cm	
501110188452	4F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS GRAFT LEFT - 100 cm	
501110188501	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 3.0 - 100 cm	7/27/2019
501110188502	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 3.5 - 100 cm	12/24/2013
501110188503	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.0 - 100 cm	7/23/2013
501110188504	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT SHORT TIP 4.0 - 100 cm	
501110188505	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.5 - 100 cm	12/6/2013
501110188506	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 5.0 - 100 cm	12/5/2013
501110188507	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 6.0 - 100 cm	
501110188508	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 3.0 - 100 cm	3/27/2014
501110188509	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 3.5 - 100 cm	12/24/2013
501110188510	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.0 - 100 cm	12/20/2013
501110188511	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.5 - 100 cm	
501110188512	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 5.0 - 100 cm	12/24/2013
501110188513	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 6.0 - 100 cm	
501110188514	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT I - 100 cm	12/24/2013
501110188525	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE A PP - 100 cm	
501110188526	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE B - 100 cm	1/10/2014
501110188527	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE B PP - 100 cm	
501110188528	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I - 100 cm	
501110188529	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II - 100 cm	
501110188530	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III - 100 cm	
501110188531	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I - 80 cm	
501110188532	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II - 80 cm	1/10/2014



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501110188533	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III - 80 cm	
501110188534	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I PP - 100 cm	
501110188535	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II PP - 100 cm	
501110188536	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III PP - 100 cm	
501110188537	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL STRAIGHT - 100 cm	12/5/2013
501110188538	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 145 - 100 cm	7/25/2013
501110188539	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 155 - 100 cm	1/10/2014
501110188540	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 3.5 - 100 cm	12/24/2013
501110188541	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 4.0 - 100 cm	12/24/2013
501110188542	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 4.5 - 100 cm	
501110188543	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	HOCKEY STICK - 100 cm	
501110188544	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PROGRESSIVE RIGHT - 100 cm	
501110188547	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	Q4 -100 cm	
501110188548	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MOD. EXTRA BACK UP - 100 cm	
501110188551	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS GRAFT RIGHT - 100 cm	12/24/2013
501110188552	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS GRAFT LEFT - 100 cm	12/24/2013
501110188601	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 3.0 - 100 cm	
501110188602	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 3.5 - 100 cm	12/18/2013
501110188515	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT II - 100 cm	12/24/2013
501110188516	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT III - 100 cm	12/24/2013
501110188517	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT I - 100 cm	12/24/2013
501110188518	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT II - 100 cm	12/24/2013
501110188519	5F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT III - 100 cm	
501110188608	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 3.0 - 100 cm	
501110188609	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 3.5 - 100 cm	12/17/2013
501110188610	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.0 - 100 cm	9/12/2013
501110188611	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.5 - 100 cm	3/28/2014
501110188612	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 5.0 - 100 cm	12/18/2013
501110188613	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 6.0 - 100 cm	
501110188614	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT I - 100 cm	11/12/2013
501110188615	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT II - 100 cm	11/12/2013
501110188616	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT III - 100 cm	12/16/2013
501110188617	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT I - 100 cm	11/12/2013
501110188618	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT II - 100 cm	11/12/2013
501110188619	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT III - 100 cm	
501110188620	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT MODIFIED - 100 cm	
501110188621	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS-LEFT - 100 cm	12/5/2013
501110188622	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS-RIGHT - 100 cm	12/5/2013
501110188623	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	INTERNAL MAMMARY - 100 cm	12/5/2013
501110188624	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE A - 100 cm	12/5/2013
501110188625	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE A PP - 100 cm	



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501110188626	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE B - 100 cm	4/6/2017
501110188603	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.0 - 100 cm	7/23/2013
501110188604	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT SHORT TIP 4.0 - 100 cm	
501110188605	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.5 - 100 cm	12/5/2013
501110188606	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 5.0 - 100 cm	12/5/2013
501110188607	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 6.0 - 100 cm	12/17/2013
501110188644	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PROGRESSIVE RIGHT - 100 cm	
501110188647	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	Q4 - 100 cm	
501110188648	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MOD. EXTRA BACK UP - 100 cm	
501110188651	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS GRAFT RIGHT - 100 cm	12/16/2013
501110188652	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS GRAFT LEFT - 100 cm	12/18/2013
501110188701	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 3.0 - 100 cm	
501110188702	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 3.5 - 100 cm	12/27/2013
501110188703	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.0 - 100 cm	7/25/2013
501110188704	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT SHORT TIP 4.0 - 100 cm	
501110188705	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 4.5 - 100 cm	12/5/2013
501110188706	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 5.0 - 100 cm	12/26/2013
501110188707	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS LEFT 6.0 - 100 cm	
501110188708	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 3.0 - 100 cm	
501110188709	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 3.5 - 100 cm	12/26/2013
501110188710	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.0 - 100 cm	12/26/2013
501110188711	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 4.5 - 100 cm	
501110188712	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 5.0 - 100 cm	12/26/2013
501110188713	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	JUDKINS RIGHT 6.0 - 100 cm	
501110188714	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT I - 100 cm	12/27/2013
501110188627	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE B PP - 100 cm	
501110188628	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I - 100 cm	12/5/2013
501110188629	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II - 100 cm	
501110188630	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III - 100 cm	
501110188631	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I - 80 cm	
501110188632	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II - 80 cm	
501110188633	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III - 80 cm	
501110188634	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I PP - 100 cm	
501110188635	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II PP - 100 cm	



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501110188636	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III PP - 100 cm	
501110188637	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL STRAIGHT - 100 cm	12/5/2013
501110188638	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 145 - 100 cm	7/25/2013
501110188639	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 155 - 100 cm	12/22/2018
501110188640	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 3.5 - 100 cm	8/29/2013
501110188641	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 4.0 - 100 cm	8/29/2013
501110188642	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 4.5 - 100 cm	6/9/2018
501110188643	6F	ALVISION INTERVENTIONAL CARDIOLOGY DC	HOCKEY STICK - 100 cm	
501110188732	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II - 80 cm	
501110188733	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III - 80 cm	
501110188734	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I PP - 100 cm	
501110188735	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II PP - 100 cm	
501110188736	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III PP - 100 cm	
501110188737	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL STRAIGHT - 100 cm	
501110188738	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 145 - 100 cm	7/24/2013
501110188739	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PIGTAIL 155 - 100 cm	
501110188740	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 3.5 - 100 cm	
501110188715	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT II - 100 cm	12/26/2013
501110188716	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ LEFT III - 100 cm	
501110188717	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT I - 100 cm	12/26/2013
501110188718	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT II - 100 cm	12/27/2013
501110188719	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT III - 100 cm	
501110188720	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	AMPLATZ RIGHT MODIFIED B - 100 cm	
501110188721	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS-LEFT- 100 cm	12/27/2013
501110188722	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS-RIGHT - 100 cm	12/27/2013
501110188723	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	INTERNAL MAMMARY - 100 cm	12/5/2013
501110188724	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE A - 100 cm	12/5/2013
501110188725	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE A PP - 100 cm	



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501110188726	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE B - 100 cm	
501110188727	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MULTIPURPOSE B PP - 100 cm	
501110188728	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I - 100 cm	
501110188729	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES II - 100 cm	
501110188730	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES III - 100 cm	
501110188731	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	SONES I - 80 cm	
501110188741	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 4.0 - 100 cm	
501110188742	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	ATESAL 4.5 - 100 cm	
501110188743	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	HOCKEY STICK - 100 cm	
501110188744	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	PROGRESSIVE RIGHT - 100 cm	
501110188747	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	Q4 - 100 cm	
501110188748	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	MOD. EXTRA BACK UP - 100 cm	
501110188751	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS GRAFT RIGHT - 100 cm	12/26/2013
501110188752	7F	ALVISION INTERVENTIONAL CARDIOLOGY DC	CORONARY BYPASS GRAFT LEFT - 100 cm	12/26/2013

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.**



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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	Single Use devices
Device Subcategory - Collective Terms (CT's per GMDN database):	
Codes:	Terms:
CT 346	Cardiology
CT 145	Cardiovascular devices
CT1582	Vascular infusion/aspiration catheters
CT 999	Radiological Devices
CT 117	Radiological systems and associated devices
CT 104	Diagnostic radiological systems and associated devices
CT 483	Angiographic x-ray systems and associated devices
CT 324	Measuring/testing
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 177	Metals
CT 201	Synthetic polymers
CT 179	Plastics
CT 212	Silicone
CT 336	Sterile
CT 130	Catheters and associated devices
CT 1581	Catheters
CT 477	Cardiovascular catheters
Generic Device Group (preferred term per GMDN database)	
Preferred Term:	Angiographic catheter, single-use
GMDN Code:	10688
Definition: A thin, flexible tube designed to inject a contrast medium into select blood vessels of the cerebral, visceral, or peripheral vasculature during an angiographic procedure in order to facilitate the clear visualization of the vascular system of a targeted organ or area of the body. It is introduced percutaneously, has a radiopaque marker(s) for positioning, and may include disposable devices dedicated to catheter introduction/function [e.g., sheath(s)]. It may also be used for simultaneous pressure measurements to determine the transvalvular, intravascular, and intraventricular pressure gradients. This is a single-use device.	



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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