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

Name of product	**Ephesos™ II Coronary Stent System**
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 (**2161507DE02**) 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: **Bare-metal coronary artery stent** GMDN Code: **53616**
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-006 Rev. 020 – 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

Ephesos™ II Interventional Cardiology Diagnostic Catheter (RA-DOC-006 Rev.020)

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) **Ephesos II** 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 stent delivery system (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 (**2161507DE02**) per *current* Directive 93/42/EEC **Annex II**.
- The Declaration of Conformity for this diagnostic stent delivery system (**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)	Coronary artery stent
Generic Device Group term	Bare-metal coronary artery stent
Product type (family)	Ephesos™ II Coronary Stent System

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:	Coronary Artery Stent System
Name Product / Device Type:	**Ephesos™ II Coronary Stent System**
Legal Manufacturer:	Alvimedica Tibbi Ürünler Sanayi ve Diş 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:	See Attachment 1.
Classification:	
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 **Ephesos™ II Coronary Stent System:**

- 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

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

Device Name / Type: **Ephesos™ II Coronary Stent System**

Indication for Use: To maintain luminal patency and improve luminal diameter typically in a patient with symptomatic atherosclerotic heart disease.

Class: Based on classification **Rule 8** of Annex IX of the Directive 93/42/EEC concerning Medical Devices, the device is considered a **Class III** device.

EPHESOS II CORONARY STENT SYSTEM CATALOGUE NUMBER

Current Reference Code	Product Definition	Manufactured Date
508110060301	2.0x9 Ephesos II Bare Metal Stent	10/25/2013
508110060302	2.0x12 Ephesos II Bare Metal Stent	12/9/2013
508110060303	2.0x15 Ephesos II Bare Metal Stent	10/8/2013
508110060304	2.0x18 Ephesos II Bare Metal Stent	6/28/2013
508110060305	2.0x20 Ephesos II Bare Metal Stent	12/9/2013
508110060306	2.5x9 Ephesos II Bare Metal Stent	9/9/2013
508110060307	2.5x12 Ephesos II Bare Metal Stent	6/14/2013
508110060308	2.5x15 Ephesos II Bare Metal Stent	6/25/2013
508110060309	2.5x18 Ephesos II Bare Metal Stent	6/20/2013
508110060310	2.5x20 Ephesos II Bare Metal Stent	5/27/2013
508110060311	2.5x25 Ephesos II Bare Metal Stent	7/10/2013
508110060312	2.5x28 Ephesos II Bare Metal Stent	9/9/2013
508110060313	2.5x32 Ephesos II Bare Metal Stent	7/11/2013
508110060347	2.75x9 Ephesos II Bare Metal Stent	6/21/2013
508110060348	2.75x12 Ephesos II Bare Metal Stent	9/4/2013
508110060349	2.75x15 Ephesos II Bare Metal Stent	5/27/2013
508110060350	2.75x18 Ephesos II Bare Metal Stent	6/25/2013
508110060351	2.75x20 Ephesos II Bare Metal Stent	5/30/2013
508110060352	2.75x25 Ephesos II Bare Metal Stent	6/25/2013
508110060353	2.75x28 Ephesos II Bare Metal Stent	10/28/2013
508110060354	2.75x32 Ephesos II Bare Metal Stent	10/28/2013
508110060314	3.0x9 Ephesos II Bare Metal Stent	8/29/2013
508110060315	3.0x12 Ephesos II Bare Metal Stent	5/24/2013
508110060316	3.0x15 Ephesos II Bare Metal Stent	6/14/2013

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Current Reference Code	Product Definition	Manufactured Date
508110060317	3.0x18 Ephesos II Bare Metal Stent	6/25/2013
508110060318	3.0x20 Ephesos II Bare Metal Stent	5/27/2013
508110060319	3.0x25 Ephesos II Bare Metal Stent	5/27/2013
508110060320	3.0x28 Ephesos II Bare Metal Stent	5/27/2013
508110060321	3.0x32 Ephesos II Bare Metal Stent	5/27/2013
508110060322	3.5x9 Ephesos II Bare Metal Stent	7/15/2013
508110060323	3.5x12 Ephesos II Bare Metal Stent	5/27/2013
508110060324	3.5x15 Ephesos II Bare Metal Stent	5/24/2013
508110060325	3.5x18 Ephesos II Bare Metal Stent	5/27/2013
508110060326	3.5x20 Ephesos II Bare Metal Stent	5/24/2013
508110060327	3.5x25 Ephesos II Bare Metal Stent	6/25/2013
508110060328	3.5x28 Ephesos II Bare Metal Stent	8/20/2013
508110060329	3.5x32 Ephesos II Bare Metal Stent	9/10/2013
508110060330	4.0x6 Ephesos II Bare Metal Stent	12/26/2014
508110060331	4.0x8 Ephesos II Bare Metal Stent	8/29/2013
508110060332	4.0x9 Ephesos II Bare Metal Stent	6/25/2013
508110060333	4.0x12 Ephesos II Bare Metal Stent	6/21/2013
508110060334	4.0x15 Ephesos II Bare Metal Stent	6/21/2013
508110060335	4.0x18 Ephesos II Bare Metal Stent	6/21/2013
508110060336	4.0x20 Ephesos II Bare Metal Stent	9/10/2013
508110060337	4.0x25 Ephesos II Bare Metal Stent	9/11/2013
508110060338	4.0x28 Ephesos II Bare Metal Stent	7/15/2013
508110060339	4.0x32 Ephesos II Bare Metal Stent	7/12/2013
508110060340	4.5x6 Ephesos II Bare Metal Stent	5/9/2014
508110060341	4.5x8 Ephesos II Bare Metal Stent	4/26/2014
508110060342	4.5x9 Ephesos II Bare Metal Stent	6/21/2013
508110060343	4.5x12 Ephesos II Bare Metal Stent	6/21/2013
508110060344	4.5x15 Ephesos II Bare Metal Stent	6/21/2013
508110060345	4.5x18 Ephesos II Bare Metal Stent	6/21/2013

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Current Reference Code	Product Definition	Manufactured Date
508110060346	4.5x20 Ephesos II Bare Metal Stent	9/12/2013

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.**

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:**
07	**Non-active implantable devices**
Device Subcategory - Collective Terms (CT's per GMDN database):	
Codes:	**Terms:**
CT 346	Cardiology
CT 1007	Body tissue manipulation and reparation devices
CT 302	Stents and associated devices
CT 2090	Stents
CT 1102	Coronary artery stents
CT 145	Cardiovascular devices
CT 752	Cardiovascular prostheses and associated devices
CT 335	Single-patient use
CT 334	Single-patient use
CT 233	Surgical
CT 301	Vascular implanted
CT 983	Surgical Invasive
CT 321	Long-term surgical invasive
CT 979	Inorganic materials
CT 177	Metals
CT 336	Sterile
CT 244	Prostheses and associated devices
CT 1370	Prostheses
CT 446	Implantable prostheses
CT 1374	Cardiovascular prostheses
CT 485	Vascular stents
Generic Device Group (preferred term per GMDN database)	
Preferred Term:	**Bare-metal coronary artery stent**
GMDN Code:	**53616**
Definition: Sterile non-biodegradable tubular device [bare metal stent (BMS)] intended to be implanted in a coronary artery or saphenous vein graft of the heart to maintain luminal patency and improve luminal diameter typically in a patient with symptomatic atherosclerotic heart disease. It may be inserted and advanced to the implantation site with a balloon catheter which will cause the device to expand upon balloon inflation, or it may be delivered by a dedicated instrument where it self-expands upon release. It is typically made of high-grade stainless steel or cobalt-chrome (Co-Cr). It may be a continuous tube, a mesh structure, or have a bifurcation design (e.g., shaped as a Y in a tube form).	

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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

	regulatory purposes (ISO 13485:2016)
MDD-93-42-EEC	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 10555-4:2013	Intravascular catheters - Sterile, single-use catheters - Part 4: Balloon dilatation catheters (ISO 10555-4:2013)
EN ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993 3:2014)
EN ISO 14630:2012	Non-active surgical implants -- General requirements (ISO14630:2012)
EN ISO 25539-2:2020	Cardiovascular implants - Endovascular devices - Part 2: Vascular stents (ISO 25539-2:2020)
ISO 5832-1:2016	Implants for Surgery - Metallic materials - Part 1 Wrought stainless steel
ASTM B912 - 18	Standard Specification for Passivation of Stainless Steels Using Electropolishing
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)
EN ISO 25539-1:2017	Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses (ISO 25539-1:2017)
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