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

Name of product	**Invader™ PTCA Balloon Dilatation 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 (**2161507DE01**) 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: **Coronary angioplasty balloon catheter, basic** GMDN Code: **47732**
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-009 Rev. 022 – Annex to the Declaration of Conformity.
Place of issue	İstanbul, Turkey

Declared by: Didem Kantar
Quality Assurance Manager

Date: 2021-05-31

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

Annex to the Declaration of Conformity
- Supporting Information –

Supporting Information to the *"Declaration of Conformity to Directive 93/42/EEC concerning Medical Devices"*

for

Invader™ PTCA Balloon Dilatation Catheter (RA-DOC-009 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) **Invader PTCA** 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 balloon (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 (**2161507DE01**) 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)	Coronary artery balloon catheter
Generic Device Group term	Coronary angioplasty balloon catheter, basic
Product type (family)	Invader™ PTCA Balloon Dilatation 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

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 angioplasty balloom catheter
Name Product / Device Type:	**Invader™ PTCA Balloon Dilatation Catheter**
Legal Manufacturer: Manufacturing location: (Final assembly) Distribution: Sterilisation location:	Alvimedica Tibbi Ürünler Sanayi ve Diş Ticaret A.Ş. İstanbul Trakya Serbest Bölgesi, Ferhatpaşa SB Mahallesi Atatürk Bulvarı No:16 34540 Çatalca-İstanbul / TÜRKİYE
Indication for Use: Classification: Catalogue (REF) numbers: List of shapes: Lot numbers:	See Attachment 1.
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 **Invader™ PTCA Balloon Dilatation Catheter:**

- 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: **Invader™ PTCA Balloon Dilatation Catheter**

Indication for Use: The ALVIMEDICA Invader™ PTCA Balloon Dilatation Catheter has been designed to dilate stenotic atherosclerotic lesions in coronary arteries or bypass grafts.

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 NUMBERS

Current Reference Code	Size	Product Definition	Manufacturing Date
512110021610	1.25X6 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021611	1.25X10 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021612	1.25X12 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021613	1.25X15 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021614	1.25X20 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021615	1.50X6 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021616	1.50X10 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021501	1.50X12 mm	Invader PTCA Balloon Dilatation Catheter	5/30/2013
512110021617	1.50X15 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021502	1.50X20 mm	Invader PTCA Balloon Dilatation Catheter	5/23/2013
512110021618	2.00X6 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021619	2.00X10 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021503	2.00X12 mm	Invader PTCA Balloon Dilatation Catheter	5/30/2013
512110021504	2.00X15 mm	Invader PTCA Balloon Dilatation Catheter	5/23/2013
512110021506	2.00X20 mm	Invader PTCA Balloon Dilatation Catheter	5/23/2013
512110021508	2.00X25 mm	Invader PTCA Balloon Dilatation Catheter	5/24/2013
512110021620	2.25X6 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021621	2.25X10 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021622	2.25X12 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021623	2.25X15 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021624	2.25X20 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021625	2.25X25 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)

512110021626	2.50X6 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021627	2.50X10 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021509	2.50X12 mm	Invader PTCA Balloon Dilatation Catheter	5/30/2013
512110021510	2.50X15 mm	Invader PTCA Balloon Dilatation Catheter	6/14/2013
512110021512	2.50X20 mm	Invader PTCA Balloon Dilatation Catheter	5/31/2013
512110021514	2.50X25 mm	Invader PTCA Balloon Dilatation Catheter	5/24/2013
512110021516	2.50X30 mm	Invader PTCA Balloon Dilatation Catheter	5/30/2013
512110021517	2.50X34 mm	Invader PTCA Balloon Dilatation Catheter	5/30/2013
512110021628	2.75X6 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021629	2.75X10 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021551	2.75X12 mm	Invader PTCA Balloon Dilatation Catheter	5/30/2013
512110021552	2.75X15 mm	Invader PTCA Balloon Dilatation Catheter	5/23/2013
512110021554	2.75X20 mm	Invader PTCA Balloon Dilatation Catheter	5/30/2013
512110021556	2.75X25 mm	Invader PTCA Balloon Dilatation Catheter	5/30/2013
512110021558	2.75X30 mm	Invader PTCA Balloon Dilatation Catheter	5/30/2013
512110021559	2.75X34 mm	Invader PTCA Balloon Dilatation Catheter	5/30/2013
512110021630	3.00X6 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021631	3.00X10 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021518	3.00X12 mm	Invader PTCA Balloon Dilatation Catheter	5/24/2013
512110021519	3.00X15 mm	Invader PTCA Balloon Dilatation Catheter	5/30/2013
512110021521	3.00X20 mm	Invader PTCA Balloon Dilatation Catheter	5/30/2013
512110021523	3.00X25 mm	Invader PTCA Balloon Dilatation Catheter	5/30/2013
512110021525	3.00X30 mm	Invader PTCA Balloon Dilatation Catheter	5/30/2013
512110021526	3.00x34 mm	Invader PTCA Balloon Dilatation Catheter	5/30/2013
512110021632	3.25X10 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021633	3.25X12 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021634	3.25X15 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021635	3.25X20 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021636	3.25X25 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)

512110021637	3.25X30 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021638	3.25X34 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021639	3.50X10 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021527	3.50X12 mm	Invader PTCA Balloon Dilatation Catheter	5/24/2013
512110021528	3.50X15 mm	Invader PTCA Balloon Dilatation Catheter	6/26/2013
512110021530	3.50X20 mm	Invader PTCA Balloon Dilatation Catheter	5/30/2013
512110021532	3.50X25 mm	Invader PTCA Balloon Dilatation Catheter	5/30/2013
512110021534	3.50X30 mm	Invader PTCA Balloon Dilatation Catheter	5/30/2013
512110021535	3.50X34 mm	Invader PTCA Balloon Dilatation Catheter	5/30/2013
512110021640	3.75X10 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021641	3.75X12 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021642	3.75X15 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021643	3.75X20 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021644	3.75X25 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021645	3.75X30 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021646	3.75X34 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021647	4.00X10 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021536	4.00X12 mm	Invader PTCA Balloon Dilatation Catheter	5/30/2013
512110021537	4.00X15 mm	Invader PTCA Balloon Dilatation Catheter	5/30/2013
512110021539	4.00X20 mm	Invader PTCA Balloon Dilatation Catheter	5/28/2013
512110021541	4.00X25 mm	Invader PTCA Balloon Dilatation Catheter	5/30/2013
512110021543	4.00X30 mm	Invader PTCA Balloon Dilatation Catheter	2/14/2014
512110021544	4.00X34 mm	Invader PTCA Balloon Dilatation Catheter	7/24/2013
512110021648	4.50X10 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021546	4.50X12 mm	Invader PTCA Balloon Dilatation Catheter	5/30/2013
512110021547	4.50X15 mm	Invader PTCA Balloon Dilatation Catheter	5/30/2013
512110021549	4.50X20 mm	Invader PTCA Balloon Dilatation Catheter	5/30/2013
512110021649	4.50X25 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021650	4.50X30 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)

512110021651	4.50X34 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021652	5.00X10 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021653	5.00X12 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021654	5.00X15 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)
512110021655	5.00X20 mm	Invader PTCA Balloon Dilatation Catheter	#N/A (New Size)

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:**
10	**Single Use devices**
Device Subcategory - Collective Terms (CT's per GMDN database):	
Codes:	**Terms:**
CT 346	Cardiology
CT 145	Cardiovascular devices
CT 123	Angioplasty system and associated devices
CT 1025	Angioplasty catheters
CT 520	Cardiac catheters and associated devices
CT 1026	Cardiac catheters
CT 1024	Cardiac balloon catheters
CT 471	Balloon-like
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 326	Manually powered/operated
CT 336	Sterile
CT 981	Single-use
CT 130	Catheters and associated devices
CT 1581	Catheters
CT 477	Cardiovascular catheters
CT 1589	Coronary angioplasty balloon catheters
CT 1590	Coronary angioplasty balloon catheters
Generic Device Group (preferred term per GMDN database)	
Preferred Term:	**Coronary angioplasty balloon catheter, basic**
GMDN Code:	**47732**
Definition: Sterile, flexible tube designed to be used in percutaneous transluminal coronary angioplasty (PTCA) to dilate a stenotic coronary artery by controlled inflation of a distensible balloon(s) at its distal tip. It is typically available as: 1) an over-the-wire (OTW) type that has a double or triple lumen, one for the guidewire and one or two for single- or double- balloon inflation; and 2) a rapid exchange (RX) type with a single lumen. It is available in various sizes for the dilatation of small, narrowed, or obstructed coronary arteries or bypass grafts. It may also be intended for pre- or post-dilatation of a balloon-expandable stent in the coronary arteries. This is a single-use device.	

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

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

List of applied 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 10555-4:2013	Intravascular catheters – Sterile, single-use catheters – Part 4: Balloon dilatation catheters (ISO 10555-4:2013)
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