Use of international generally acknowledged state-of-the-art standards in the absence of harmonised standards under the IVDR and MDR

As outlined in the Standardisation Regulation 1025/2012, standardisation, in general, contributes to the functionality of the internal market and plays a vital role in international trade. However, harmonisation of standards is a strictly European concept, where a European standard is developed based on the standardisation request from the European Commission to provide solutions for compliance with the legal provisions.

For European manufacturers, harmonised standards have been and remain the preferable tool to support product safety and performance given their legal value in providing a presumption of conformity with the General Safety and Performance Requirements (GSPR) of the respective legislation. Nevertheless, standards are a voluntary means[1], and the devices must first and foremost be in conformity with the relevant respective legislations, and not a standard, regardless of whether or not it is harmonised.

The new Regulations on Medical Devices 2017/745/EU (MDR) and *In-Vitro* Diagnostic Medical Devices 2017/746/EU (IVDR) support the use of harmonised standards[2], however, given current progress, it is questionable that harmonised standards for the new regulatory framework will be available on time, especially by the date of application of the MDR. The Commission and the Competent Authorities are working together with the European Standardisation Organisations to finalise the standardisation request, which is required for harmonisation to take place.

During this time of uncertainty and in the absence of harmonised standards, industry is concerned about inconsistent and possibly arbitrary approach to the application of standards as a reference and benchmark for safety and performance.

A possible solution forward is to apply the proposed ranking model:

- The state-of-the-art versions of standards which are harmonised under the current Directives;
- Other published standards identified as candidates for harmonisation under the respective Regulation, or;
- Appropriate international and European consensus standards (ISO/ IEC or EN), given that harmonised standards are mostly originated from them.

The ISO and IEC standards provide a tool for compliance with the different requirements for the European and International markets and are globally recognised as state-of-the-art standards. Of note, former Global

[1] Regulation 1025/2012/EU on European standardisation
[2] Article 8 of 2017/745/EU and 2017/746/EU

Harmonisation Task Force (GHTF)[3] and International Medical Device Regulators Forum (IMDRF)[4] have already encouraged the Regulatory Authorities to recognise the use of international standards as a means of demonstrating conformity with the Essential Principles.

MedTech Europe has developed in association with its members, a set of criteria that manufacturers can use in the absence of harmonised standards (Annex I and II of this document). Manufacturers may need to use multiple standards to demonstrate state of the art performance and this document provides support for choosing these in an appropriate and defined manner. MedTech Europe would urge the manufacturers to utilise and the Notified Bodies to consider the state-of-the-art standards as the means to provide appropriate levels of product safety and performance.

About MedTech Europe

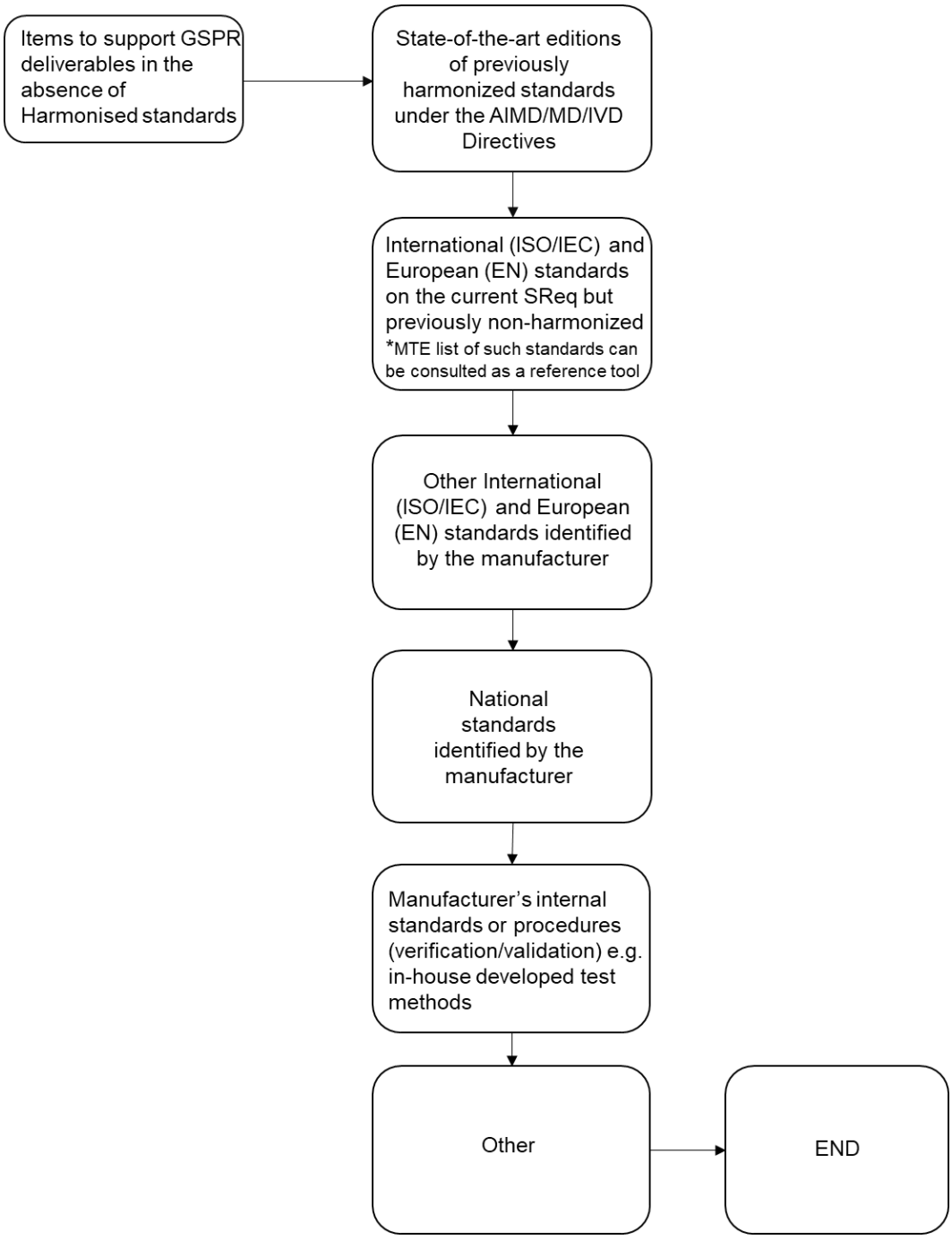
MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

For more information, visit www.medtecheurope.org.

[3] GHTF/SG1/N044:2008

[4] IMDRF PD1/N51 (http://www.imdrf.org/docs/imdrf/final/consultations/imdrf-cons-optimisting-standards-n51-180524.pdf)

ANNEX I – Hierarchy of standards



* List of standards can be found in Annex II of this document

Please note that depending on a product in question, it is manufacturer's sole responsibility to choose an appropriate and applicable standard.

ANNEX II

Standards considered for harmonisation under the IVDR or MDR, respectively, which have not been harmonised under the current Active Implantable Medical Devices Directive (AIMDD 30/385/EEC), Medical Devices Directive (93/42/EEC) and *In-Vitro* Diagnostics Medical Devices Directive (IVDD, 98/79/EU).

PART A: In-Vitro Diagnostic Medical Devices Regulation (746/2017/EU)

EN/ISO/IEC	***Standard***	***Title***	***Comment***
ISO	11135	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices	Replaces parts 1 and 2
ISO	11607-1	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems	
ISO	11607-2	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes	
ISO	17665-1	Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	
ISO	20857	Sterilization of health care products — Dry heat — Requirements for the development, validation and routine control of a sterilization process for medical devices	
ISO	20916	In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice	New standard #
ISO	25424	Sterilization of health care products — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices	

PART B: Medical Device Regulation (745/2017/EU)

EN/ISO/IEC	*Standard*	*Title*	*Comment*
ISO	10993-10	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization	
ISO	10993-23	Biological evaluation of medical devices — Part 23: Tests for irritation	New standard #
ISO	11135	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices	Replaces part 1 and 2
ISO	14160	Sterilization of health care products — Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives — Requirements for characterization, development, validation and routine control of a sterilization process for medical devices	
ISO	14708-1	Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer	
EN	14885	Chemical disinfectants and antiseptics. Application of European Standards for chemical disinfectants and antiseptics	

ISO	17664-2	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices	New standard [#]
ISO	20417	Medical devices — Information to be provided by the manufacturer	New standard [#]
ISO	20857	Sterilization of health care products — Dry heat — Requirements for the development, validation and routine control of a sterilization process for medical devices	
ISO	23908	Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling	
ISO	25424	Sterilization of health care products — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices	
IEC	60601-1-12	Medical Electrical Equipment — Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment	

[#] New standard refers to the first edition of a standard, either already published or in preparation