



TECHNICAL REPORT ON Standards for EU Medical Device Regulatory Compliance

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1. Overview

This report offers medical device manufacturers with an overview of the role of technical standards in delivering medical device regulatory compliance and in achieving standardization and harmonization. It explores the sources of technical standards, the differences in their various

editions and versions, as well as priority considerations when determining the use of various sources as well as how to deal with uncertainty when priority sources are not available.

The following are explored and/or referenced:



EU Medical Device Regulation (MDR)

The EU MDR regulates the legal and technical requirements (including [General Safety and Performance Requirements](#) and the use of harmonized standards) of general Medical Devices in the EU.



2017/746 EU In Vitro Diagnostic Medical Devices Regulation (IVDR)

The EU IVDR regulates the legal and technical requirements (including [General Safety and Performance Requirements](#) and the use of harmonized standards) of In Vitro Diagnostic Medical Devices in the EU.



Official Journal (OJ) of the European Union

The EU's Official publication (gazette) for communicating regulatory updates including EU Regulations and the harmonized standards lists.



EU Blue Guide

Non-binding guidance on the implementation of EU product rules, particularly for CE-marked products, including medical devices. It is intended for various stakeholders, including manufacturers, importers, distributors, market surveillance authorities, and consumers.



2. Exploring technical standards for EU medical device regulatory compliance

2.1. Role of technical standards

The EU Blue Guide (Chapter 1.1) provides a historic overview of the EU legislation of goods, and how in the “New Approach” era, the use of standards has helped to detach technical requirements from legal requirements. Technical requirements undergo change more frequently to align with technological progress and to comply with what is deemed ‘state-of-the-art,’ while legal requirements rarely undergo change and are also cumbersome to revise.

Currently, MDR (Article 8) states:

“Devices that are in conformity with the relevant harmonized standards, or the relevant parts of those standards, the references of which have been published in the Official Journal of the European Union, shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof.”

There are a few important observations to make about this provision:

- The use of harmonized standards is *generally not mandatory* (except for EN ISO 15223-1 and other applicable harmonized standards, including symbols – explicitly required by MDR Annex I, GSPR 23.1(h) if the use of symbols is appropriate).
- If the manufacturer chooses not to use the applicable existing harmonized standards (i.e. not use any standards or use other standards), the Notified Body (NB) expects the manufacturer to prove that its solution produces a medical device that is at least as safe and effective as if it had used the harmonized standard(s). Usually, this takes the form of a detailed gap assessment between the applicable harmonized standard clauses and the manufacturer’s solution. Avoiding the use of harmonized standards altogether is typically not possible (i.e. to cut costs). Examples include (amongst others):
 - The harmonized standard includes an error (typo, ambiguous description) either in the technical requirement or in the method of testing/assessment (i.e. if the manufacturer conforms to the technical requirement, the EUT (equipment under test) would always fail the test). The manufacturer looks at the previous edition of the standard, in which this test remained the same and discovers that the decimal point was misplaced in the latest version. The manufacturer uses the parameters from the previous standard version.
 - The harmonized standard includes one or more self-contradictions (e.g., EN ISO 14971:2012) and cannot be logically applied in full; the manufacturer must justify how it has resolved the contradiction to reach the best result for its device.

- The manufacturer operates in multiple product sectors (i.e. aerospace, defense and medical devices), and its in-house technology (i.e. welding process) parameters do not strictly follow the medical device harmonized standards, but through sufficiently robust testing it can be proven that the end result of the process (i.e. factor of safety for the mechanical strength of a weld seam) meets or surpasses the requirement of the harmonized standard.
- An extreme, real-life case that occurred: the Official Journal of the European Union (OJ) links on the europa.eu website were misdirecting, causing the list of harmonized standards for another EU Directive (recreational marine equipment) to be shown instead of the EU Medical Device Directive (MDD). In this case, a manufacturer could easily justify that it used the last known version of the MDD harmonized standard list.
- Based on the above, Notified Bodies (NBs) cannot establish nonconformities purely because a manufacturer does not comply with a standard requirement, unless the manufacturer either:
 - Claims compliance with the harmonized standard (this equally applies to other external standards, guidelines or specifications or parts thereof); or
 - There is evidence that the manufacturer’s solution is inferior (less safe or resulting in lower effectiveness) to that required by the harmonized standard, without proper justification.
- A typical situation is a completely omitted requirement due to the manufacturer being unaware of the standard or due to the manufacturer’s misinterpretation of its contents.
- The above article also makes it clear that a harmonized standard should be considered applicable even if not all normative clauses are applicable. Therefore, as long as at least one requirement in a clause from a harmonized standard is applicable, the standard as a document is considered applicable. The manufacturer typically justifies the applicability of the clauses through a checklist or test report form (TRF).

Under the [New Legislative Framework](#), manufacturers shall determine if their medical devices are in scope for other EU product regulations (i.e. containing or being medicinal products, PPE, machinery, etc.) and should consider the use of relevant harmonized standards as applicable, as well as consulting the [EU Blue Guide](#).

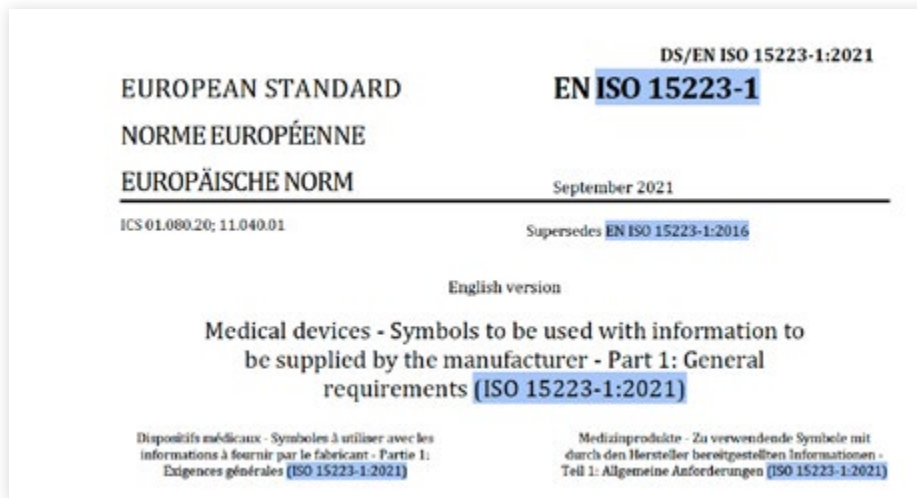
The above presumption is also possible in part because harmonized standards represent what is deemed state-of-the-art. As such, they also fit into the risk model of the MDR by meeting the criteria set out through the GSPRs, demonstrating the reduction or risk as much as possible. The role of international product safety standards in risk management is explained in the ISO/TR 24971 guideline.

2.2. Standardization and harmonization process

The [EU Blue Guide](#) (Section 4.1.2) provides additional information on the adoption and harmonization of standards.

Technical standards (that end up being harmonized) or ‘standard families’ are usually created by expert groups (consisting of various industry stakeholders, like the ISO TCs) from recognized standardization organizations, such as ISO, IEC or CEN/CENELEC. These groups consider the industry’s consensus of what state-of-the-art is, and in many cases, must fit into a standardization or regulatory framework. Proposed drafts are circulated, and in some cases are published for public comment. A vote for the standard’s release then takes place with the standard usually following a naming convention of a nomenclature consisting of the standardization body’s abbreviated name and an identification number, including a part number suffix in case of a standard series, such as ISO 15223-1.

As a next step towards harmonization, international standards (published by international standardization organizations) must be adopted as European standards. This is performed by ESOs listed in Annex I of Regulation (EU) No 1025/2012 (CEN, CENELEC and ETSI). Following this process, the European version gets an EN (European Norm) prefix (thus, for example, ISO 15223-1 becomes EN ISO 15223-1), in some cases replacing the original prefix (i.e. IEC 60601-1 becomes EN 60601-1). And it gets a “European foreword” (with no change to the base content). Note that due to the time required for the adoption process, the issue date of the European version is sometimes the same but can also be later than the original standard publication date.



Relevant European standards may then be evaluated to determine if their content is suitable to be used to prove compliance with the requirements of certain directives or regulations. If the relevant expert body finds that the standard represents a match in the scope, value system (including compatibility with any existing larger standardization frameworks) and requirements, they consider the standard contents to be **harmonized**. This does not change the

standard prefix or other part of the nomenclature, but:

- The harmonized standard is typically amended with certain Annexes (one for each regulation to which they are harmonized), which typically include tables mapping the coverage of the standard with the GSPRs and other requirements of the regulation:



I.S. EN ISO 13485:2016&LC:2016&AC:2018&A11:2021		
EN ISO 13485:2016/ A11:2021		
Requirements of Article 10 of Regulation (EU) 2017/ 745	Clause(s) / sub-clause(s) of this EN	Remarks/ Notes
9, 2 nd paragraph	4, 5, 6, 7, 8	Covered.
9, 3 rd paragraph (a)	4.1.1, 7.3.9	Partially covered. EN ISO 13485 requires that the organization identifies applicable regulatory requirements and incorporates them in its quality management system. An explicit requirement for a documented regulatory strategy is not included. Control of design and development changes is explicitly specified.



Note: Not all EN standards are harmonized standards, but all harmonized standards are EN standards.

Most EU member states have national standardization bodies as well, which may additionally naturalize European standards, thus making them **national standards**. The contents are typically identical to the European standard with an additional cover page identifying the document as a national standard. The standard nomenclature is prefixed with the abbreviation of the national standardization body (i.e. an EN ISO standard may become BS EN ISO or DIN EN ISO, CEI EN ISO, MSZ EN ISO, etc.). Naturalization, which can include translation, can take additional time, so the issue date of national standards can differ from their EN counterpart. In many cases, this is the only version (and not the EN version) that can be purchased from the web store of the standardization bodies. Comparing price points is recommended since the cost offered per standardization body might vary. It should be noted that the technical content should be identical to ensure that the notified body will accept this without any problem.

Also, it is worth noting that ESOs and some national standardization bodies develop standards themselves, which also have the same prefixes as international standards. For example, the EN 13485 standard is completely different from the EN ISO 13485 standard. The former covers guidelines for food thermometers, while the latter covers

quality management system requirements for medical device manufacturers.

To provide perspective, some other major jurisdictions also follow a process with various degrees of similarity, resulting in a collection of standards and other specifications like the OJ harmonized standard list, such as:

- UK: Designated standards – GOV.UK (www.gov.uk)
- USA: Recognized Consensus Standards: Medical Devices (fda.gov)
- Canada: List of Recognized Standards for Medical Devices – Canada.ca
- Japan: Certification standards (as part of Certification Criteria, in connection with the Essential Requirements) are defined for some (but not all) JMDN codes.
- China: China Institute of Food and Drug Control – medical device standards and classification management (nifdc.org.cn)
- Australia: Standards orders and medical devices | Therapeutic Goods Administration (TGA)

2.3. Differences between various versions and editions of technical standards

When a standard is initially created (or revised), it goes through several predefined draft stages (see e.g., the ISO deliverables), where each draft stage has a unique prefix. The various draft prefixes (e.g., CD vs. DIS vs. FDIS) reflect the maturity and reliability of the included text relative to the final version, in so far as a final draft is likely to be identical to the published standard, more so than a DIS or a CD draft. When a manufacturer is in the position to obtain access to such versions, it is usually beneficial to assess the proposed content or the change in content, compared to a previous version or predecessor standard, and carry out a preliminary gap assessment.

After publication, the standard can undergo different levels of changes as defined by the IEEE Standards Association:

- **Amendment:** "A document that adds to, removes from, or alters material in a portion of an existing IEEE standard and may make editorial or technical corrections to that standard."
 - indicated by A or AMD [optional sequential number of amendments] [optional issue date of amendment], e.g., A1, A2 after the standard reference.
- **Corrigendum:** "A document that only corrects editorial errors, technical errors, or ambiguities in an existing IEEE standard."
 - indicated by AC or COR. [optional sequential number of corrigendum] [optional issue date of corrigendum], e.g., EN ISO 13485:2016/AC:2018 after the standard reference.
- **Erratum:** "A document that contains only grammatical corrections to, or corrections of errors introduced during the publishing process of, an existing IEEE standard."
 - indicated by ERR [optional sequential number of errata] [optional issue date of erratum], e.g. ERR1, ERR2 after the standard reference.

These changes can be published as:

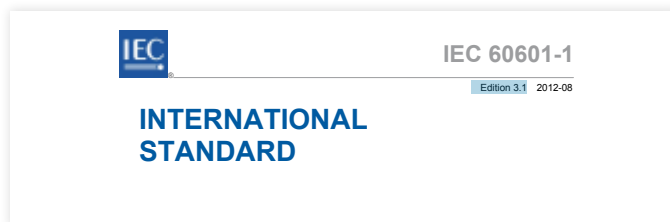
- Differential/delta/gap/redline document (with a conventional sign of a forward slash "/"; e.g., EN IEC 60601-2-83:2020/A11:2021), which will only show which content (clauses, paragraphs, sentences, diagrams, tables, etc.) needs to be removed, replaced, or added.
- Consolidated versions (with a conventional sign of a plus "+"; e.g., EN 285:2015+A1:2021) will only show the updated content (sometimes visually highlighting the changed content).

The two publications styles are often available for purchase, and each has its pros and cons; a consolidated version is a better baseline, while a delta version can help with gap analysis after a substantial change. Ultimately, the manufacturer can construct its own working copy simply by having the original document and one of the associated modifications (both should be identical in technical content).

This is important as the standards are expensive to begin with, considering the number of different processes and product standards a typical manufacturer needs and the ~3-year update cycle for product standards and modifications. With respect to modifications (e.g., a corrigendum that is only a few sentences), these occasionally sell for almost the same price as the full original standard. The manufacturer may consider subscribing to the full standard catalogue of a standardization body, which sometimes offers a preview of the full content of the standard before purchase.

Similarly, the references are also convertible between the two styles, e.g., EN ISO 25424:2019 + EN ISO 25424:2019/A1:2022 = EN ISO 25424:2019+A1:2022, and as such, the manufacturer can use the appropriate combinations of references in its QMS and product documentation.

Standards can undergo multiple editions (~generations or major revisions) under the same reference number, which can sometimes be indicated on the standard cover page:



This is helpful when referencing a given level of the standard rather than referencing issue dates and amendments due to the plethora of different versions that might exist concurrently, along with differences in dates of issuance due to adoption and naturalization. This complexity is depicted below.

Medical electrical equipment –
Part 1: General Requirements for basic safety and essential performance
(IEC 60601-1:2005 + Cor.:2006 + Cor.:2007 + A1:2012);
German version EN 60601-1:2006 + Cor.:2010 + A1:2013

Additionally, a given version of a standard (or its modification) may be translated into different languages and made available at the same time. The various versions are typically identified by a language code after the standard reference, i.e. EN ISO 11737-1:2006 + AC:2009 (D) is a German version, while EN ISO 19011:2011 (D/E) is a German/English bilingual version and EN ISO 9000:2005 (D/E/F) is a trilingual version. These references are useful to ensure purchasing the right language version of a standard.

Due to a technical standard's objective to represent what is deemed state-of-the-art at a given period, each standard has a limited lifetime (typically 3-4 years for product standards and 6-10 years for system and process standards). At the end of the lifecycle of the standard, it will be either withdrawn (if it no longer serves a purpose) or may be merged/split into other document(s).

When a harmonized standard approaches this end-of-life stage (or the relevant expert group determines that the standard no longer represents content that can be used to presume conformity for any reason), the OJ will be updated to include a date of withdrawal (see column 6 in the table below), which is also the date of end of presumption of conformity (see MDR Article 8). Under MDD, this was the DOCOPOCOSS (Date of Cessation of Presumption of Conformity of the Superseded Standard). This may be an immediate switch to the succeeding standard (like in the example below, where after 2023-07-05 only the amended version of EN ISO 25424:2019 can be used to presume conformity) or a transition period may be announced (historically, a 3-year transition was typical for major standard editions, like EN 60601-1 Ed2 to Ed3).

**Medical electrical equipment –
Part 1: General requirements for basic safety and essential performance
(IEC 60601-1:2005 + Cor.:2006 + Cor.:2007 + A1:2012);
German version EN 60601-1:2006 + Cor.:2010 + A1:2013**

Depending on the interval between the OJ update and the date of withdrawal (an immediate or later date), the enforcement from the notified body (NB) will differ, as follows:

- If the effect is immediate, depending on the prior availability of the draft revisions, all stakeholders (manufacturers, test labs and NB personnel alike) will need to carry out a gap assessment and, depending on the differences identified, an action plan (quality plan) will be formulated and executed by the manufacturer. The NB in this case follows the manufacturer's roadmap and enforces active management of the transition (i.e., ensures that there are no unjustified delays). For some critical updates, however, it may be decided by the NBs (often explicitly required by the Competent Authorities) that no new units of the products are released before the transition is complete.
- If there is a set timeline for the transition (e.g., 3 years), then, assuming the devices are in continuous production, the manufacturer's roadmap should fit within the allotted timeframe. In this case, the NB may also enforce a transition plan that ensures a steady pace of progress (that is, for example, ensures that not all activities, such as the gap assessment, redesign and third-party testing, are crammed into the last couple of months of the transition period).

These actions include the following next steps:

- No action necessary (if the changed section of the new revision is not applicable to the manufacturer's product).
- Redesign (+ re-testing as applicable).
- FSCA (field safety corrective action, including recall or field repair as applicable).
- Complete retirement of the product if, considering the state-of-the-art described in the new standard, the manufacturer's risk analysis determines that the units in the field are potentially unsafe or not effective.

Often manufacturers align their product design and development strategy along these major standard revisions – i.e., the current/previous generation of the product is compliant with the current edition of the standard, but will not be redesigned simply to comply with the next edition, rather it will be retired as soon as the next generation of the product (compliant with the next editions of the applicable standards and incorporating other new customer requirements) comes to market.



2.4. Priority considerations when using various sources of technical standards

Derived from the above, primarily, EN standards harmonized to the MDR/IVDR can be used to presume conformity with MDR/IVDR requirements (respectively).

What happens if there is no harmonized standard listed for an aspect of the Quality Management System, its applicable processes, or the product, but there are known standards

from other sources that are widely regarded to represent what is currently deemed state-of-the-art? In this case, the manufacturer may fall back on standards (where standards may instead mean technical recommendations, guidelines, datasheets, etc.) that represent informative or normative content from other sources in the following priority:

- 1 Harmonized standard
- 2 International standard
- 3 National standard
- 4 In-house or other industry standards

For every level of fallback, the manufacturer shall justify its use of the given standard level, e.g., when resorting to using a national standard, the manufacturer should explain that the use of the standard is beneficial to the product safety and effectiveness, but that there is no comparable harmonized or international standard available for the same scope.

Note: This consideration and priority can be applied not only to the whole standard but also to sections thereof, i.e. clauses from an international standard may augment (but generally do not replace) the requirements of a harmonized standard which has the same general scope but lacks the same provision.

Since the current list of MDR harmonized standards is significantly shorter than the previous MDD harmonized standard list, a typical situation that manufacturers face when working on MDR technical documentation is relying on standards that used to be harmonized under MDD but that are not harmonized under MDR.

In this case, these need to be treated (selected, used, and justified) as international standards with no harmonized equivalent. However, sole reliance cannot be based on the MDD harmonized standard list (last updated on 2021-04-15), as the international standards may have been amended, which now represent what is currently deemed state-of-the-art.

In this case, the method is as follows:

Step	Example	Result
Find out the equivalent version of the previous harmonized standard (i.e. for an EN ISO standard, use the ISO version. For an EN standard, there is a chance that it was published by CEN or IEC).	From the MDDTD, check if the following can be used: <ul style="list-style-type: none"> • EN 60601-1:2006/AC:2010 • EN 60601-1:2006/A1:2013 (IEC 60601-1:2005/A1:2012) (last harmonized version) 	The international standard is the IEC 60601-1. The standardization body is the IEC.
Verify the current version of the international standard and acquire the current version if newer than the last harmonized version.	Visit the IEC web shop and search for 60601-1	The current version is: IEC 60601-1:2005 +AMD1:2012 +AMD2:2020 Since it has the AMD2, which would be A2 of the EN version, which we do not have, purchase either: <ul style="list-style-type: none"> • the standalone amendment (IEC 60601-1:2005/AMD2:2020) or • the consolidated version
Evaluate standard gaps and assess applicability.	[One gap example] It is found in the risk analysis of a battery-operated medical device that the risk of reversed polarity was not considered, which is now explained in more depth in clause 7.3.3.	It is assessed that AMD2 is (at least partially) applicable, so the revision of the battery replacement risk to the RMF as an action item is added to the transition plan.
Due to the lack of a harmonized version, a clause coverage mapping table (MDR – IEC 60601-1 Ed 3.2) needs to be created. * See section 3.	Use the following sources: <ul style="list-style-type: none"> • Annex Z* of the last harmonized version of EN 60601-1 • Compiled MDD ER – MDR GSPR mapping tables from the Internet or a sample list at the end of this document (verify before use) Check if the amendments altered the chapter numbers (including whether new chapters were added).	A table that shows which MDR requirements can be covered by complying with the latest version of IEC 60601-1.
Execute the compiled transition action list (redesign, re-testing).	Go through the whole Design History File (DHF) of the product; start with top-level product requirements to design validation. With the test lab that performed your previous testing, discuss and determine which tests need to be repeated vs reused. Update the test plan.	A new medical device file: potentially changed DHF, Device Master Record, and overall revised MDR technical documentation
Lodge an application with a notified body if a conformity assessment needs to be performed.		MDR application MDR Technical Documentation review report MDR Certificate



Another typical scenario is that the international standard is already updated (or there is a mature public draft circulated) and the community deems it to represent the state-of-the-art, but the harmonized standard is not yet available/indicated in the OJ. In this case, the manufacturer can easily justify the use of the non-harmonized standard that surpasses the harmonized one

and the notified bodies will typically have no problem accepting the latest version of the standard as a tool to presume compliance with the MDR GSPRs. This is especially the case if the standard reference number is the same – this is not a strict requirement, however, the burden of proof is higher if the standard reference number has changed.

3. MDD Essential Requirements to MDR General Safety and Performance Requirements

Essential Requirements = ERs				General Safety and Performance Requirements = GSPRs			
MDD ER	MDR GSPR	MDD ER	MDR GSPR	MDD ER	MDR GSPR	MDD ER	MDR GSPR
1, 2, 3	1	9.2	14.2(f)	12.8.1	21.1	13.3(b)	23.3(e)
2	2	9.2	14.2(g)	12.8.2	21.2	13.3(h)	23.3(f)
-	3	9.3	14.3	12.9	21.3	13.3(g)	23.3(g)
2	4	-	14.4	-	22	13.3(l)	23.3(h)
1	5	14.1	14.5	-	23.1(a)	13.3(e)	23.3(i)
4	6	10.2	14.6	13.1	23.1(b)	13.3(i)	23.3(j)
5	7	-	14.7	-	23.1(c)	13.6(a)	23.4(a)
6	8	10.1, 10.3	15	13.1	23.1(d)	13.4	23.4(b)
6(a)	MDR Annex IX, Chapter II, Section 5.2	11.1	16.1(a)	-	23.1(e)	-	23.4(c)
-	9	11.4	16.1(b)	-	23.1(f)	-	23.4(d)
7.1	10.1	11.2.1	16.2(a)	-	23.1(g)	13.6(b)	23.4(e)
7.2	10.2	11.2.2	16.2(b)	13.2	23.1(h)	-	23.4(f)
7.3	10.3	11.3	16.3	13.3(c)	23.2(a)	13.6(e)	23.4(g)
7.5	10.4	11.5.1	16.4(a)	13.3(b), 13.4	23.2(b)	13.6(d), 13.6(p)	23.4(h)
7.6	10.5	-	16.4(b)	13.3(a)	23.2(c)	13.6(i)	23.4(i)
-	10.6	11.5.2	16.4(c)	13.3(a)	23.2(d)	13.3(j), 13.6(a)	23.4(j)
8.1	11.1	11.5.3	16.4(d)	13.3(n)	23.2(e)	13.6(d)	23.4(k)
-	11.2	12.1	17.1	7.5	23.2(f)	13.6(g)	23.4(l)
-	11.3	12.2	17.2	13.3(d)	23.2(g)	13.6(h)	23.4(m)
8.3	11.4	-	17.3	-	23.2(h)	13.6(h)	23.4(n)
8.4	11.5	-	17.4	13.3(e)	23.2(i)	-	23.4(o)
8.5	11.6	12.1	18.1	13.3(l)	23.2(j)	13.6(h)	23.4(p)
8.6	11.7	12.2	18.2	13.3(i)	23.2(k)	13.6(c)	23.4(q)
8.7	11.8	12.3	18.3	13.3(c), 13.3(m)	23.2(l)	13.6(j)	23.4(r)
7.4	12.1	12.4	18.4	13.3(k)	23.2(m)	13.6(k), 13.6(l), 13.6(m)	23.4(s)
-	12.2	12.5	18.5	13.3(f)	23.2(n)	-	23.4(t)
7.4	13.1	-	18.6	-	23.2(o)	-	23.4(u)
8.2	13.2	12.6	18.7	13.3(g)	23.2(p)	13.6(n)	23.4(v)
-	13.3	-	18.8	13.3(h)	23.2(q)	-	23.4(w)
9.1	14.1	-	19.1	-	23.2(r)	-	23.4(x)
9.2	14.2(a)	-	19.2	13.3(d)	23.2(s)	13.6(q)	23.4(y)
9.2	14.2(b)	-	19.3	13.3(c)	23.3(a)	-	23.4(z)
7.3	14.2(c)	-	19.4	-	23.3(b)	-	23.4(aa)
-	14.2(d)	12.7	20	13.3(m)	23.3(c)	-	23.4(ab)
7.6	14.2(e)	-	20.5	13.3(a)	23.3(d)	-	-

*In a generic MDD-MDR transition case, this would be the first step, i.e. you generally map the differences between the MDD Annex I ERs and the MDR Annex I GSPRs and then try to find the standards (harmonized or other) to prove compliance with applicable GSPRs.

When you need to be sure

