General Safety and Performance Requirements

A comparison of Annex I of the new MDR versus the Essential Requirements of the current MDD

Within the final draft of the new MDR (February 2017, "*Position of the Council at first reading with a view to the adoption of a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC*"), the current 13 Essential Requirements were replaced by 23 General Safety and Performance Requirements.

Unfortunately, the proposed MDR doesn't provide a trace matrix between the current and the new requirements. The following table was compiled to provide such comparison. Although it was actually quite difficult to align the new requirements one-by-one with the current requirements, the table may be supportive when manufacturers are asked to establish a revised checklist for the conformity assessment under the new MDR.

General Safety and Performance Requirements within the proposed the new MDR	Current 13 Essential Requirements within MDD 93/42(EEC
1. Performance, safety, effectiveness	ER1
2 Reduce risks as far as possible	n/a
3 Risk Management System	n/a
4 Risk Control Measures	ER2
5 Use Error	ER 1
6 Lifetime of the device	ER4
7 Transport and Storage	ER5
8 Known and foreseeable risks, side effects	ER6
9 Devices listed in Annex XV	n/a
10 Chemical, physical and biological properties • 10.1 • 10.2 • 10.3 • 10.4 • 10.5 • 10.6	ER7 • 7.1 • 7.2 • 7.3 • 7.5 • 7.6 • n/a

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General Safety and Performance Requirements

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General Safety and Performance Requirements within the proposed the new MDR	Current 13 Essential Requirements within MDD 93/42(EEC
11 Infection and microbial contamination • 11.1 • 11.2 • 11.3 • 11.4 • 11.5 • 11.6 • 11.7 • 11.8	ER8 • 8.1 • n/a • n/a • 8.3 • 8.4 • 8.5 • 8.6 • 8.7
12 Devices incorporating a substance considered to be a medicinal product • 12.1 • 12.2	ER7.4
13 Devices incorporating materials of biological origin • 13.1 • 13.2 • 13.3	ER8 • 7.4 • 8.2 • n/a
14 Construction of devices and interaction with their environment • 14.1 • 14.2 • 14.3 • 14.4 • 14.5 • 14.6 • 14.7	ER9 • 9 • 9 • 9 • n/a • n/a • 10.2 • n/a
15 Devices with a diagnostic or measuring function • 15.1 • 15.2	ER10 • 10.1 • 10.3
16. Protection against radiation • 16.1 • 16.2 • 16.3 • 16.4	ER11 • 11.1, 11.4 • 11.2 • 11.3 • 11.5

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General Safety and Performance Requirements within the proposed the new MDR	Current 13 Essential Requirements within MDD 93/42(EEC
17. Electronic programmable systems • 17.1 • 17.2 • 17.3 • 17.4	ER 12 • 12.1 • 12.1 • n/a • n/a
18 Active devices and devices connected to them • 18.1 • 18.2 • 18.3 • 18.4 • 18.5 • 18.6 • 18.7 • 18.8	ER12 • 12.6 • 12.2 • 12.3 • 12.4 • 12.5 • n/a • 12.6 • n/a
19 Particular requirements for active implantable devices • 19.1 • 19.2 • 19.3 • 19.4	(taken from AIMDD) • (ER 8) • (ER 9) • (ER11) • (ER12)
20. Protection against mechanical and thermal risks • 20.1 • 20.2 • 20.3 • 20.4 • 20.5 • 20.6	ER 12.7 • 12.7.1 • 12.7.2 • 12.7.3 • 12.7.4 • n/a • 12.7.5
21. Protection against the risks posed to the patient or user by supplied energy or substances • 21.1 • 21.2 • 21.3	ER 12.8 • 12.8.1 • 12.8.2 • 12.9

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General Safety and Performance Requirements

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General Safety and Performance Requirements within the proposed the new MDR	Current 13 Essential Requirements within MDD 93/42(EEC
22. Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons • 22.1 • 22.2 • 22.3	n/a, (ER3)
23. Label and instructions for use • 23.1 • 23.2 • 23.3 • 23.4	ER13 • 13.1, 13.2 • 13.3, 13.4 • 13.3 • 13.5, 13.6

Contents of the current ER6a is not listed anymore within the Annex I of the proposed MDR. The requirement for a clinical evaluation is now described within article 49 and Annex II of the MDR

This information is provided for free and the author does not take any responsibility for the contents included. However, in order to improve this table continuously, please inform the author in case any errors or gaps are found.

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