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REGULATORY REQUIREMENTS OF THE NEW MDR (EU) 2017/745

Your industry, our focus

After Work Event
„Marktzutritt Medical Devices in EU, USA und Brasilien“

Hotel Thessoni classic
Eichwaatt 19, 8105 Zürich-Regensdorf
07.11.2018 – 15.00 – 18.00

EXTRACT PRESENTATION

DR. PETER DIESING

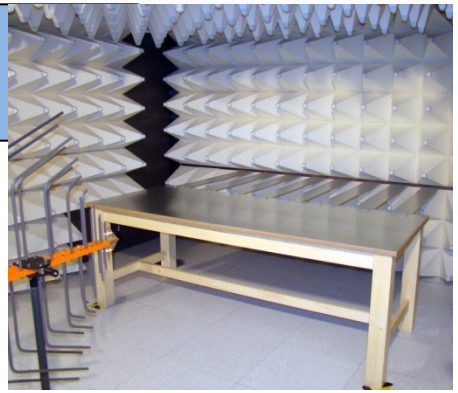
EUROFINS PRODUCT SERVICE GMBH

Eurofins Product Service - Germany

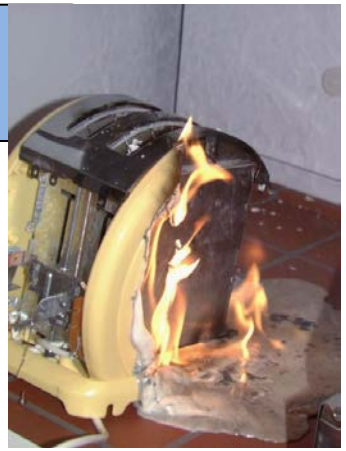
Your industry, our focus

Radio / Wireless

EMC

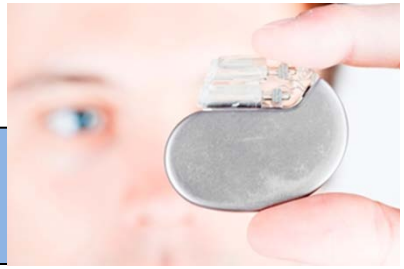


Product Safety



Environment

Certification



Comparison Structure MDR – MDD I

Annex MDR	Content	Annex in MDD 93/42/EEC	Requirement in MDD
I	General safety and performance requirements	**Annex I**	Essential requirements
II	Technical documentation	**Annex II, III and VII**	Described in Annex II, III and VII
III	Technical documentation on post-market surveillance	**Not described in MDD**	Described in MEDDEV 2.12/1
IV	EU declaration of conformity	**Not described in MDD**	National requirement in Germany Ek-Med 3.9 A4
V	CE marking of conformity	**Annex XII**	CE Marking
VI	UDI Information	**Not required**	-
VII	Requirements to be met by notified bodies	**Annex XI**	CRITERIA TO BE MET FOR THE DESIGNATION OF NOTIFIED BODIES
VIII	Classification rules	**Annex IX**	CLASSIFICATION CRITERIA
IX	Conformity assessment based on a quality management system and assessment of the technical documentation	**Annex II**	EG-KONFORMITÄTSERKLÄRUNG (Vollständiges Qualitätssicherungssystem)

Comparison structure MDR – MDD II

Annex MDR	Content	Annex in MDD 93/42/EEC	Requirement in MDD
X	Conformity assessment based on type examination	**Annex III**	EC TYPE-EXAMINATION
XI	Conformity assessment based on product conformity verification	**Annex V and Annex VI**	EC DECLARATION OF CONFORMITY
XI - A)	PRODUCTION QUALITY ASSURANCE	**Annex V Annex VI**	(Production quality assurance) (Product quality assurance)
XI – B)	PRODUCT VERIFICATION	**Annex IV**	EC VERIFICATION
XII	Certificates issued by a notified body	**Not described**	Described in NBOG document NBOG BPG 2010-3
XIII	Procedure for custom-made devices	**Annex VIII**	STATEMENT CONCERNING DEVICES FOR SPECIAL PURPOSES
XIV	Clinical evaluation and post-market clinical follow-up	**Annex X MEDDEV 2.12/2**	Annex X, Chapter 1

Comparison structure MDR – MDD III

Annex MDR	Content	Annex in MDD 93/42/EEC	Requirement in MDD
XV	Clinical investigations	**Annex X**	Annex X, Chapter 2
XVI	List of groups of products without an intended medical purpose referred to in Article 1(2)	**Not included in MDD**	-
XVII	Correlation table	**Not included in MDD**	-

Resources

- **NEW! Person responsible for placing on the market (Art. 15)**
- **Comparable to the safety officer according to § 30 MPG, but**
- **with extended area of responsibility**
  - **Responsibility for compliant manufacture and final testing,**
  - **Keeping the technical documentation**
  - **Post-market monitoring**
  - **Reporting obligations under Articles 87 - 91 (vigilance)**
- **Can be outsourced by small and very small enterprises**
- **European authorised representative must also have permanent and permanent access to this resource.**

Summary

- **MDR is based on the New Approach used so far!**
- **Changes need to be applied for all manufacturers (e.g. TD, PSUR)**
- **Introduction of new procedures in area IIb for drug administration and class III for implants**
- **Introduction of a new class Ir (class reusable)**
- **Software highly likely to be affected by reclassification**

- **Project management is highly recommended for the implementation of the new requirements!**

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BRAZILIAN CERTIFICATION PROCCESS

Your industry, our focus

EXTRACT PRESENTATION

November 07th, 2018 - Servus Souza da Silva

Particular requirements

General requirements for any kind of device are described by Portaria #118:2015

For each one of devices requiring certification has a Particular Portaria

Particular portarias are:

- Medical devices: Portaria #54:2016 (starts on 2017-05-01)
- IT equipment: Portaria #170:2012
- Appliances and machinaries: Portaria #371:2009

INMETRO has 155 Particular Portarias available

Particular requirements (cont.)

Medical devices

Medical devices has the certification running through Portaria 54: 2017, but the madatory certification is defined by ANVISA

ANVISA is Sanitary Vigilance Agency and belongs to Brazilian Healthy Ministry

The ANVISA rules are defined inside the Normative Instruction no. 4 (IN 04:2015)

Normative Instruction no. 4 (IN 04:2015) has a whole list of IEC standards where the certification is mandatory.
Normative Instruction no. 4 (IN 04:2015) had its Annex I and Annex II updated through Normative Instruction no. 22 (IN 20:2017)

Model of certification is Model 5

Type tests

Factory audit

Particular requirements (cont.)

Type tests are based on IEC 60601 series of standards

General standard – IEC 60601-1. Edition 3.1

Collateral standard – IEC 60601-1-2 (EMC)

Collateral standard – IEC 60601-1-6 (Usability + IEC 62366)

Collateral standard – IEC 60601-1-8 (Alarms)

Collateral standard – IEC 60601-1-9 (Environmentally Conscience Design)

Particular Standard – IEC 60601-2-X (for each one of devices)

The Risk Management file based on ISO 14971 and Software based on IEC 62304 shall be considered for evaluation

Extract presentation

EUROFINS | MET LABS

*Take your products to market **fast** and **easy** with* **Eurofins | MET** Labs

R. Roland Gutzky Jr.
Sector Business Development Manager

Business Lines

*Take your products to market **fast** and **easy** with* **Eurofins | MET Labs**

Service scope, at a glance

EMC

- Regulatory testing for FCC, IC, EMC and RED Directive
- Wireless testing and certification
- Military
- Avionics
- Automotive

Environmental & Energy

- Military standards
- NEBS
- Automotive
- Energy Star (test lab and certification agency)
- Battery
- Failure Evaluation

Product Safety & Certification

- NRTL – The MET Mark
- CB Scheme
- CE marking
- Global Market Access

Accreditations

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NRTL

ACCREDITED
Baltimore Certificate
0591-01

DSCC Approved

CB Canada

TRANSIT TESTED

Standards Council of Canada
Accredited Certification Organization
Conseil canadien des normes
Organisme de certification accrédité
TM

NVLAP

NB/CAB

NCB/CBTL

ANSI
ANSI Accredited Program
PRODUCT CERTIFICATION

VCI

FC

Singapore IDA

TCB

Wi Fi

Global Market Access

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NOM

INMETRO

EAC

CE

VCCI

Nationally Recognized Testing Laboratory (NRTL) Program

Question: Who is responsible for ensuring that a product, used in a workplace, bears an NRTL mark?

Answer: The burden rests with the employer where the product is ultimately used.

Differences between North America and Europe

North America

- Evaluations must be conducted by approved, independent laboratories
- Regular factory inspections are required to maintain certification
- Strong emphasis on pre-approved components

Europe (LVD/EN)

- Evaluations can be done by the manufacturer or outsourced to a laboratory
- No Factory Inspections are required, however manufacturer must be prepared to demonstrate continued compliance if challenged
- Components and be evaluated in the end-use application

FDA Submissions – De Novo

De Novo application (de novo = 'new')

Novel devices of low to moderate risk that do not have a valid predicate device

Advantages

- A De Novo can operate like a patent of sorts, because a manufacturer can define what makes the device unique and depending upon whether that technology is proprietary, it can create substantial obstacles for would-be competitors.
- There is a higher priority assigned to pre-sub meetings given to De Novo submissions; you may get in sooner

Disadvantages

- It takes longer
- It creates a predicate for future competitors
- More expensive

FDA Submissions – De Novo

vs.