Boston® Materials
MDR-Lounge

46th Annual EFCLIN Congress 2019
Brussels, Belgium
(25th April to 27th April)

Thank you for visiting the Boston® Materials MDR-Lounge at EFCLIN 2019.

Based on the great feedback from last year's supporting materials, we have updated this document. Our goal is to link you, our lab customer, to the most recent and relevant information possible. In order to do that we have provided brief overviews on certain aspects of the MDR since the last EFCLIN Congress, and supplemented these with a comprehensive list of web-links.

We hope that you find this supporting material helpful during your ongoing transition work to meet the requirements of EU 2017/745 MDR.

Contained within this updated support document you will find:

- An overview of the recently published corrigendum to the Medical Device Regulation.
- The importance of up-to-date material safety data and how Boston® Materials have addressed this requirement.
- Understanding CMR & ED substances in relation to material assessments.
- Overview of the evolving requirements of Post-Market Surveillance & Vigilance (*taken from the recent MDCG working group summary report provided to EUROMCONTACT).*
- A comprehensive list of web-links to general information pages and external information resources. *(All information in the listed web-links is free of charge and in the public domain).*
- Details of the supporting European and National trade associations representing our industry.

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The Medical Device Corrigendum (March 2019)

The first corrigendum to the MDR was published on 13th March 2019. A review of the content shows that the corrections are all minor, with no additional requirements being made - (see the summary below).

- 2 instances of rewording / simplification of the sentence:
  - Pages 89 and 148.
- 2 instances of minor date changes:
  - Page 69 (twice).
- 2 instances of spelling corrections (same correction twice):
  - Pages 17 and 22.
- 4 instances of clarification of detail:
  - Pages 132, 140, 149 and 169.
- 6 instances of reference corrections:
  - Pages 25, 66, 90, 148 and 149 (twice).

The full (multi-language) Corrigendum document (15409/1/18 Rev 1) can be downloaded using the link to the Commission website that is listed in the **Useful web links** section towards the back of this document.

Updated material safety data

Following on from the EFCLIN Congress in 2018, the Boston® Materials team committed to conducting a review and update (as required) on its material safety data across the full range of materials.

The full suite of test data (biocompatibility, physicochemical, shelf-life and lens stability) – per the requirements of ISO 18369 parts 3 and 4, and the applicable parts of ISO 10993 - is available on demand to all European lab customers.

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We provide test data reports on a USB flash drive or will provide a link to a shared Dropbox folder. Ask at the Boston® Materials booth at EFCLIN for more detail, or email alan.bennett@bausch.com.

Understanding substances of very high concern and the required safety assessments for device materials.

MDR Annex 1 – General Safety and Performance Requirements
Section 10.4 Substances (page 96):

Specific requirement is now made for devices, including invasive devices (e.g. contact lenses), to include justifications for the use of any substances of very high concern (SVHC) that are in a concentration that is above 0.1% weight by weight (w/w).

The following sub-sections outline the requirements:

- 10.4.1 describes what substances are categorised as such.
- 10.4.2 describes the requirements concerning the justifications.
- 10.4.3 extends to the guidelines on phthalates.
- 10.4.4 extends to the guidelines on CMR and ED substances.
- 10.4.5 describes the requirements around device labelling for devices containing a higher than 0.1% (w/w) concentration of any substances described above.

Key definitions:

- **SVHC**
  - **S**ubstances of **V**ery **H**igh **C**oncern, i.e., CMR or ED substances.
- **CMR**
  - Substances known to be **C**arcinogenic, **M**utagenic or toxic to **R**eproduction.
- **CMR Category 1A substances**
  - **Known** human **C**arcinogen (H340), **M**utagen (H350) or **R**eproductive toxicant (H360) based on human evidence.

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- **CMR Category 1B substances**
  - **Presumed** human **C**arcinogen (H340), **M**utagen (H350) or **R**eproductive toxicant (H360) based on animal studies.

- **ED**
  - Substance with **E**ndocrine **D**isrupting properties. Endocrine disruptors are chemicals which under certain conditions can impact on the hormonal system of humans and animals.

- **Phthalates**
  - Phthalates are a group of chemical substances used to soften plastics. Some phthalates have shown adverse effects on the reproductive and endocrine systems.

Contact lens materials are clearly the key component in any contact lens, and therefore must be assessed at an individual chemical component and volume level to establish how they must be considered within these requirements.

The Boston® Materials team completed a full search of the ECHA database in 2018 and are delighted to confirm that all Boston® Materials are formulated with components that are not identified as SVHC.

A formal written statement is available – for provision to your Notified Body - and is supplied, along with the biocompatibility and physicochemical analysis reports upon request. Please email alan.bennett@bausch.com.

If you wish to understand more about the formulation of our materials then come along to the Boston® Materials booth at EFCLIN and take the opportunity to meet and talk with Ken Harty, Senior Operations Manager at our RGP materials manufacturing facility in Wilmington, MA (US). Ken will be working with the team throughout the entire EFCLIN Congress.

For further information on the European Chemicals Agency database, and for detailed information on current chemical listings and new additions see the links to the ECHA and ChemSafetyPro websites listed in the **Useful web links** section towards the back of this document.

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Post-Market Surveillance & Vigilance – the evolving requirements.

MDR Annex III – Technical documentation on post-market surveillance (page 112) in accordance with Articles 83-86. Manufacturers need to systematically and actively gather information in the post-market phase of the overall product lifecycle to demonstrate an active role in the post-market phase.

Shown below is a brief outline of the requirements of each of the relevant Articles:

Article 83 – Post-market surveillance system of the manufacturer.
For each device - Manufacturers are required to draw up, document, implement and maintain a post-market surveillance plan. This must be appropriate for the type of device and proportionate to the risk class.

The key message is that the manufacturer must take an active role in gathering, analysing and acting upon post-market data to demonstrate effective lifecycle management of each device placed upon the market.

Article 84 – Post-market surveillance plan (PMSP).
The post-market surveillance system developed by the manufacturer, per the requirements of Article 83 (above), must be based upon a documented plan – the PMSP. The requirements are set out in the first section of Annex III.

Article 85 – Post-market surveillance report (PMSR).
Applies to class I devices only.
The PMSR is used to summarise the results and conclusions of the analysis of the post-market surveillance data that has been gathered per the PMSP. The report should be updated as required and must be constantly made available to the relevant national Competent Authority.

Article 86 – Periodic safety update report (PSUR).
Applies to class IIa, class IIb and class III devices.
Follows similar requirements to those described in Article 85 except that the PSUR – determined by class and risk category – shall be updated at least annually (for class IIb and class III), and at least every two years for class IIa devices. The PSUR shall form part of the Technical Documentation as described in Annexes II and III.

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Guidance Documents vs. Implementing Acts

At the recent MDCG working group meeting (Post-market surveillance and vigilance – PMSV), the representatives from the MDCG (acting in their technical capacity to the EU Commission), stated that a concerted effort is being made to limit the development of Implementing Acts to support the implementation of the MDR. The preference is to further develop, and update, the existing Meddev guidance documents that are currently used to support the MDD.

One key guidance document being worked upon is **Meddev 2.12/1– Guidelines on a medical devices vigilance system.** This can be accessed via the **Guidance documents list (current Directives)** link located within the **Useful web links** section towards the back of this document.

Using the link will take you to the most up-to-date version of the guidance document and – crucially – to the current versions of key forms, e.g., the MIR (Manufacturer's Incident Reporting form).

The technology challenge within post-market surveillance and vigilance needs to be understood and addressed as soon as possible by manufacturers as there is a tightly controlled timeline that must be adhered to. For detailed requirements refer to Articles 87 through 90.

The new (updated) MIR (Manufacturer's Incident Report) form.

The new MIR is the result of ongoing work for 3 years and supports the transition move from the MDD to the MDR. The new version has been approved by the MDCG and was published on the website during January 2019. The new form can be used with immediate effect (optional) but must be used by January 2020 (mandatory). Manufacturers must adapt their database systems to allow for direct data transfer (machine to machine) to the EUDAMED system. All old-style form templates will be removed from January 2020.

The existing PSR (Product Safety Report) form – linked to the MIR.

This is an existing tool for manufacturers to use within the requirements of the current MDD. The intention is for this to become a harmonized web-based form that can be used to feed into the MIR form, and only becomes applicable in May 2020 and only for the MDR.

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The new PSUR (Product Safety Update Report) form.

This is a new mechanism and is applicable only to the MDR and only deals with devices registered in the EUDAMED system – so does not include custom-devices.

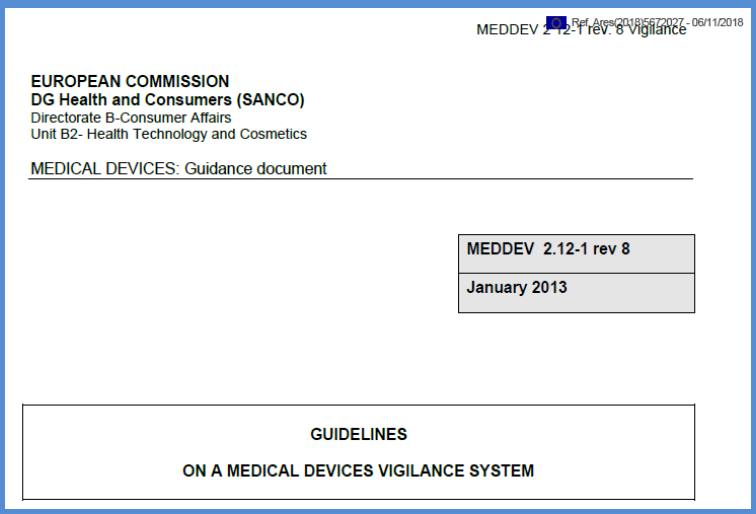
FSCA requirements – (Field Safety Corrective Actions), covering FSN (Field Safety Notices) and FSCAR (Field Safety Corrective Action Reporting).

This requirement will present a substantial potential technology challenge for manufacturers due to the very specific requirement data transfer requirements that are likely to be required – machine to machine into the EUDAMED system.

Transparency of information.

There is an expectation of a level of transparency in all post-market surveillance and vigilance data within the public domain. A key aspect of the MDR is to increase both the field of vision and the time scales involved in the monitoring of the performance of devices placed on the market. Performance is focused on both safety and efficacy of the device – and always with the intention of protecting patient safety whilst also supporting the development and provision of innovative products to enhance the lives of patients.

The full report from the MDCG Expert Working Group – Post-Market Surveillance & Vigilance meeting that was held on 5th March 2019 is available as PDF. Please visit the Boston® Materials booth at EFCLIN or email: alan.bennett@bausch.com for a copy.



MEDDEV 2.12-1 rev. 8 vigilance

Ref. Ares(2018)5672027 - 06/11/2018

EUROPEAN COMMISSION
DG Health and Consumers (SANCO)
Directorate B-Consumer Affairs
Unit B2- Health Technology and Cosmetics

MEDICAL DEVICES: Guidance document

MEDDEV 2.12-1 rev 8
January 2013

GUIDELINES

ON A MEDICAL DEVICES VIGILANCE SYSTEM

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Useful web links (EU links available in multiple languages)

EU Commission:

- **Regulation (EU) 2017/745 MDR**
  - EC Europa - MDR
- **Corrigendum to (EU) 2017/745 MDR**
  - 15409/1/18 Rev 1
- **Guidance documents list (current Directives)**
  - https://ec.europa.eu/growth/sectors/medical-devices/current-directives/guidance_en
- **Scientific Committee on Health, Environment and Emerging Risks**
  - SCHEER
- **Medical Devices (market sector information)**
  - http://ec.europa.eu/growth/sectors/medical-devices/
- **Medical Devices (links to external resources)**
  - https://ec.europa.eu/growth/sectors/medical-devices/library_en

European Chemical Agency (an agency of the European Union):

- **Candidate List of substances of very high concern for Authorisation**
  - https://echa.europa.eu/candidate-list-table

Independent chemicals resource:

- **ChemSafetyPro**
  - https://www.chemsafetypro.com/

Independent regulatory supporting information:

- **EMERGO by UL (excellent site providing free independent resource)**
  - https://www.emergobyul.com/resources

Notified Body association:

- **Team-NB: The European Association Medical Devices – Notified Bodies**

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European / National trade associations

EUROMCONTACT	Secretary General - pascale.rouhier@euromcontact.eu **https://euromcontact.org/**
EFCLIN	Secretariat – info@efclin.com **https://www.efclin.com/**
MEDTECH EU	info@medtecheurope.org https://www.medtecheurope.org/
Germany – SPECTARIS	info@spectaris.de **http://www.spectaris.de/**
Italy – ASSOTTICA	segreteria@assottica.it **http://www.assottica.it/**
Netherlands – NAC	Secretary General – nac@brabers.nl
Spain - AEO	Secretariat - secretaria@aeo.es **http:/www.aeo.es/**
Switzerland – OPTICS	Secretariat - info@ch-optics.ch http://www.ch-optics.ch/
United Kingdom – ACLM	Secretary General – secgen@aclm.org.uk **http://www.aclm.org.uk/**

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Our commitment

Boston® Materials is committed to providing continuing support to its valued Customers throughout the MDR transition period and beyond.

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