3M Deutschland GmbH

Carl-Schurz-Straße 1
41453 Neuss

☎+49 (0)2131/140
🖷+49 (0)2131/142649
Internet: www.3M.de
E-Mail: innovation.de@3M.com
WEEE-Reg.-Nr. DE 36963167
VAT-ID: DE 120679179

EU-MDR Confirmation Letter and Distributor Requirements

(For Distributors in the European Union)

Neuss, July 1 2022

The intent of this document is to clarify, for **3M medical products ("3M Medical Devices")**, if regulated by the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices ("EU-MDR")*:

- our obligations, in our economic operator roles as legal manufacturer, authorized representative and importer, respectively per articles 10, 11 and 13 of the EU-MDR as being relevant in context of the co-operation with you as distributor of 3M Medical Devices;
- your obligations as distributor in your cooperation with 3M in our economic operator roles for globally sourced medical devices.

This document is subject to the terms of any supply agreement between you and 3M with respect to the 3M Medical Devices or, in the absence of a supply agreement, to 3M's standard terms and conditions of sale. The sale of 3M Medical Devices is subject exclusively to such supply agreement or, in the absence of a supply agreement, the respective standard terms and conditions of sale which are deemed to have been accepted without reservation by the purchaser at the latest when he takes delivery of 3M Medical Devices.

Depending on the 3M Medical Device, 3M may hold multiple "Economic Operator" roles as defined in the EU-MDR*. Those are "Manufacturer" (*Art. 10* of EU-MDR), "Authorised Representative" (*Art. 11* of EU-MDR), and "Importer" (*Art. 13* of EU-MDR), the latter applying to 3M Medical Device under the regulatory responsibility of 3M entities located outside of the European Union.

*Guidance from the Document of the Medical Device Coordination Group is to be considered as applicable: MDCG 2021-25 "Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC"

We confirm the following requirements are met concerning a 3M Medical Device being placed onto the EU market by us:

- The 3M Medical Device is CE marked and the EU declaration of conformity of the 3M Medical Device is issued.
- The 3M Medical Device is accompanied by the information to be supplied in accordance with *Article 10 (11)* of EU-MDR, if applicable.
- A unique device identification (UDI) number has been assigned for the 3M Medical Device.
- 3M is ISO 13485 certified and thus has established and maintains systems for tracing, complaint handling and vigilance.
- Labeling includes instructions for 3M Medical Devices subject to special storage or transportation conditions, if applicable.
- Registration obligations for legal manufacturer, authorized representative, and importer per *Articles 10 (7), 11 (3c)* and *13 (4)* of EU-MDR in EUDAMED have been or will be met per the applicable due dates in EUDAMED.
- Documents to be verified by distributors according to *Art. 14* of EU-MDR, such as the Declaration of Conformity, Instructions for Use, etc., will be made available for download on "HCBGregulatory.3M.com" as 3M Medical Devices transition to EU-MDR.

The above information is considered to be sufficient to meet your obligations as distributor according to *Art. 14* and *Art. 25* of EU-MDR.

As a distributor of 3M Medical Devices within the EU, you shall comply with the applicable provisions of the EU-MDR, namely *Art. 14* and *Art. 25*.

With focus on our co-operation, you shall comply with all your obligations as a distributor, including, but not limited to:

- Referring to *Article 14 (4)* of EU-MDR*, concerning a **suspected non-conforming 3M Medical Device:**
  - immediately inform the 3M legal entity(ies) indicated as manufacturer and, where applicable, as authorized representative and importer;

co-operate with the appropriate 3M legal entity(ies), and with your competent authority to ensure the necessary corrective action is taken to bring the 3M Medical Device into conformity, to withdraw or to recall it, as appropriate.

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devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC"

- Referring to *Article 14 (5)* of EU-MDR*, concerning complaints or reports received from healthcare professionals, patients, or users about **suspected incidents related to a 3M Medical Device:**
  - immediately forward this information to the appropriate 3M legal entity(ies) using the following email addresses :
  - meddev.de@mmm.comfor medical devices (Medical Division)
  - sbmed@mmm.comfor Dental Products (Oral Care Division)
  - meddev.utk@mmm.com for Orthodontic products (Unitek)
  - keep the appropriate 3M legal entity(ies) informed of your monitoring via a register of
    - complaints,
    - non-conforming 3M Medical Devices,
    - recalls and withdrawals,

    and provide them with any information upon 3M request.

- Referring to *Article 25* of EU-MDR, concerning the **identification within the supply chain:**
  - co-operate with the 3M legal entity(ies) indicated as manufacturer or authorised representative to achieve an appropriate level of traceability of 3M Medical Device. This would include recording name and address of the shipping package consignee.

In specific, contact your 3M representative, or notify 3M legal entity(ies) at the contact information provided in DIMDI / EUDAMED upon 3M's registration, or at the addresses indicated on the labeling / IFU.

For additional information, please contact your local 3M representative.

Margaret Bessenbach

Margaret Bessenbach
Director Regulatory Affairs and Quality, EMEA
Health Care Business
3M Deutschland GmbH

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