MED CERT®

Certification. Medical Only.

# EC Certificate of Conformity

**The Notified Body**

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH**
**Pilatuspool 2 – 20355 Hamburg – Germany**

herewith certifies that the company:

**DMG Chemisch-Pharmazeutische Fabrik GmbH**
**Elbgaustraße 248**
**22547 Hamburg**
**Germany**

has introduced, applies and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

## Annex II without section 4

This certification is subject to surveillance by MEDCERT.

**Effective date:** **2020-12-21**
**Expiry date:** **2024-05-27**

Report No.: 0302FS28F
Process No.: QS – 0302
Certificate No.: 0302GB410201221A

Hamburg, 2020-12-21

MEDCERT Certification Body
(Dr. Andreas Schich)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

MEDCERT Identification Number: 0482

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## Appendix of EC Certificate of Conformity

Process No.: QS – 0302
Certificate No.: 0302GB410201221A

**List of products / product categories included in the scope of certificate**

**Dental materials and -instruments**

- **Luting materials (cements, polymers)**
- **Dentine and enamel adhesives**
- **Endodontic filling materials**
- **Materials for Desensitization**
- **Materials for generative production (3D printing) of dental forms (polymers)**
- **Plastic materials for direct insertion (polymers, metals)**
- **Temporary filling materials**
- **Temporary crown- and bridge materials**
- **Rotary instruments for connection to dental handpieces (surgically invasive)**
- **Protective films (varnish)**
- **Protective films (long term)**
- **Core build-up materials**
- **Cavity lining materials**
- **Relining materials**
- **Materials for fixed prostheses (inlays, onlays, crowns, bridges, veneers)**
- **Materials for removable prostheses and other intraorale appliances (polymers, ceramics)**
- **Materials for surface preparation (etch, prime)**
- **Temporary luting materials**

– End of list –

To whom it may concern

DNV MEDCERT GmbH
Pilatuspool 2
20355 Hamburg
Germany

Tel: +49 40 2263325-0
E-mail: Medcert-Info@dnv.com

**Date**: 2024-03-13

**Our reference**: QS-0302

**Notified Body Confirmation Letter**
**Certification No: 0302GB454240313**

**Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices**

To whom it may concern,

This letter confirms that DNV Medcert GmbH, a Notified Body (NB), designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0482 on Nando[1], has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer.

DMG Chemisch-Pharmazeutische Fabrik GmbH
Elbgaustraße 248
22547 Hamburg
Germany
SRN[2]: DE-MF-000006027

The devices covered by the formal application and the written agreement mentioned above are identified in the tables (in the appendix of this letter). Table 1 identifies the devices for which an MDR application has been received, a written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by 20 March 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by EU 2023/607), are shown below:

[1] Nando (New Approach Notified and Designated Organisations) Information System, https://ec.europa.eu/growth/tools-databases/nando/.
[2] Single registration number (SRN) according to Article 31 (2) of MDR.

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding well established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa devices, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

For DNV MEDCERT GmbH

Monika Hamann
Customer Service Manager

Appendix (see following pages):

- Table 1 and Table 2
- Revision history

Appendix

**Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| **Pre-formed resins and dental crowns** | Class IIa | N/A | Certificate 0302DE410201221A* NB0482 |
| **Orthodontic devices - other** | Class IIa | N/A' | Certificate 0302DE410201221A* NB0482 |
| **Temporary dental cements** | Class IIa | N/A' | Certificate 0302DE410201221A* NB0482 |
| **Dental conservation composites** | Class IIa | N/A | Certificate 0302DE410201221A* NB0482 |
| **Dental bonding agents** | Class IIa | N/A' | Certificate 0302DE410201221A* NB0482 |
| **Dental restoration glass ionomers** | Class IIa | N/A' | Certificate 0302DE410201221A* NB0482 |
| **Enamel-dentinal etching materials** | Class IIa | N/A | Certificate 0302DE410201221A* NB0482 |
| **Dental impression silicones** | Class IIa | N/A' | Certificate 0302DE410201221A* NB0482 |
| **Dental impression materials - other** | Class IIa | N/A' | Certificate 0302DE410201221A* NB0482 |
| **Prosthetic dentistry devices - other** | Class IIa | N/A | Certificate 0302DE410201221A* NB0482 |
| **Dental burs and abrasive disks, single-use** | Class IIa | N/A' | Certificate 0302DE410201221A* NB0482 |
| **Materials for the preparation of custom-made dental devices - other** | Class IIa | N/A' | Certificate 0302DE410201221A* NB0482 |
| **Castable dental posts** | Class IIa | N/A' | Certificate 0302DE410201221A* NB0482 |

*also exists in English language 0302GB410201221A

**Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| **None** | None | None | None |

**Confirmation Letter Revision History:**

| Date | NB internal reference traceable to each version of the letter | Action |
|---|---|---|
| 2024-03-13 | 0302GB454240313 | Initial issue |