dent a pharm
Produktionsgesellschaft mbH
competence in private-label

dent a pharm · Schusterring 35 · 25355 Barmstedt/Germany

Schusterring 35 · 25355 Barmstedt/Germany
Fon: +49 4123 / 92 25-0 · Fax: +49 4123 / 92 25-48
info@dent-a-pharm.de · www.dent-a-pharm.de
Steuernummer: 18 295 14920 · Ust.-Id.: DE811596681
Amtsgericht Pinneberg · HRB 1335 EL
Geschäftsführer:
Joachim Pein · Dr. Wolfgang Willmann

Barmstedt, 28.11.2023

Explanation

Dear Sir or Madam,

In 1994 the company "dent a pharm" was founded and began the production with light curing tray material (material for fabrication of individual custom tray / blanks) "unlabled" for the private label market. In the course of time further private label products of high quality for dental laboratories and for dentistry use got into their range.

In the year 1998 the company "Willmann & Pein GmbH" was founded. The idea for start up with "W & P" was to create an own label. Since many years both companies are producing light curing composites, temporary cements, A-Silicones, glas-ionomer-cements, prophylaxis and bleaching materials, LiWa and different other products.

In the year 2022 the management of both companies decided to change the responsibilities of both companies due to a request of our Notified Body, with the intention of bringing about a clearer division of the two companies.

Therefore the following changes occurred:

- The company Willmann&Pein GmbH, located at Schusterring 35,41a, 25355, Barmstedt in Germany is no longer acting as a manfucaturer. Therefore the company Willmann&Pein will only perform the tasks of a distributor.
- The company Dent-A-Pharm Produktionsgesellschaft mbH, located at Schusterring 35,41a, 25355, Barmstedt in Germany, will completely perform the tasks of the manufacturer
- The UDI-code for all products will change from the WP-identifier "+EUWP" to the DP-identifier "+D932".

Both companies are still located at the exact same address and nothing else has changed except for the shift of the manufacturer and its address on the packaging materials.

Willmann & Pein GmbH
Schusterring 35
25355 Barmstedt
Fon: +49 4123 9228-0
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dent a pharm
Produktionsgesellschaft mbH
Schusterring 35, 25355 Barmstedt
Fon: +49 4123 9225-0
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Joachim Pein
(Managing director)

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: 2024-04-26

Our reference: QS-1592

Notified Body Confirmation Letter
Certification No: 1592GB454240426

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.

dent a pharm Produktionsgesellschaft mbH
Schusterring 35
25355 Barmstedt
Germany
SRN[2]: DE-MF-000012922

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.

[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.

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:

- 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
Non-active dental implants and dental materials	Class IIa	N/A	Certificate 1592DE414210309A NB0482 Certificate 1592GB414210309A NB0482
Non-active non-implantable dental materials	Class IIa	N/A	Certificate 1592DE414210309A NB0482 Certificate 1592GB414210309A NB0482

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
N/A	N/A	N/A	N/A

Confirmation Letter Revision History:

Date	NB internal reference traceable to each version of the letter	Action
2024-01-15	1592GB454240115	Initial issue
2024-04-26	1592GB454240426	Addition of MDN 1103 and MDN 1209

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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:

dent a pharm Produktionsgesellschaft mbH
Schusterring 35
25355 Barmstedt
Germany

with locations listed in the appendix

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 V

This certification is subject to surveillance by MEDCERT.

Effective date: **2021-03-09**
Expiry date: **2024-01-20**

Report No.: 1592PS22F
Process No.: QS – 1592
Certificate No.: 1592GB414210309A

Hamburg, 2021-03-09

MEDCERT Certification Body
(Lorenz Runge)

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

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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 – 1592
Certificate No.: 1592GB414210309A

List of locations included in the scope of certificate

dent a pharm Produktionsgesellschaft mbH
Schusterring 41a
25355 Barmstedt
Germany

– End of list –

This appendix is integral part of the above-referenced certificate.
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Appendix of EC Certificate of Conformity

Process No.: QS – 1592
Certificate No.: 1592GB414210309A

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

Dental filling materials

- **Filling and luting materials**
- **Pulp capping materials**
- **Varnishes**
- **Etching gels**
- **Adhesives**

– End of list –

This appendix is integral part of the above-referenced certificate.
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