TÜV NORD Certification

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TÜV®

Our / Your Reference	Contact	Direct Dial	Date
ZA 3528 0833 / Reg. No. 44 235 202395 Date of notification: 2022-04-08 Confirmation No. 001	TÜV NORD CERT Medical Email: medical@tuev-nord.de	Phone:	2022-04-08

Written confirmation of the correction or addition of information on valid certificates in accordance with Directive 93/42/EEC, taking into account the provisions of Regulation (EU) 2017-745, Article 120.

Written confirmation correcting or supplementing information on valid certificates in accordance with Directive 93/42/EEC, taking into account the provisions of Regulation (EU) 2017-745, Article 120.

TÜV NORD CERT GmbH, Notified Body for medical devices, identification number 0044.
TÜV NORD CERT GmbH, Notified Body for medical devices, identification number 0044

In accordance with the provisions of Regulation (EU) 2017/745, Article 120, certificates issued under Directive 93/42/EEC that are still valid may no longer be changed. This letter confirms corrections or additions to information on the following valid certificate.

In accordance with the provisions of Regulation (EU) 2017/745, Article 120, certificates issued under Directive 93/42/EEC that are still valid may no longer be changed. This letter confirms correcting or complementing information of the following valid certificate.

Manufacturer

dentona AG
Otto-Hahn-Str. 27
44227 Dortmund Germany

Conformity assessment procedure

93/42/EEC Annex V

Reg. No.

44 235 202395

Report No.

3528 0833

Date of issue	*Valid from*	*Valid until*	*Edition*
2021-01-19	2021-01-19	2023-09-23	1
2022-04-08	2022-04-08	September 23, 2023	Correction 001 / *Correction 001*

Reason for change

Order of the Central Authority of the German States for Health Protection with regard to Medicinal Products and Medical Devices (ZLG) dated January 19, 2022
Report on compliance with requirements by the Central Authority of the German States for Health Protection in the Field of Medicinal Products and Medical Devices (ZLG) dated March 22, 2022
Order of the Central Authority of the German States for Health Protection with regard to Medicinal Products and Medical Devices (ZLG) of January 19, 2022
Report on the fulfillment of conditions by the Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices (ZLG) of March 22, 2022

Change

The description of the scope *"Non-active implantable* products" is adapted to the issued Annex 1 of the certificate and thus made more precise.
The description of the scope "Non-active implantable products" is adapted to Annex 1 of the certificate and thus made more precise.

Confirmed scope

Dental products: Restorative materials, dental; Composite restorative materials, dental, heat-cured

Dental products: Restorative Materials, Dental; Composite Restorative Materials, Dental, Heat-Cured

Annex 1, Reg. No.

44 235 202395

Report No.

3528 0833

Date of issue	*Valid from*	*Valid until*	*Edition*
2021-01-19	2021-01-19		1

Reason for change

See page 2

Change

See page 2

Confirmed scope

Class IIa products *Products of class IIa*	Type *Type*	UMDNS
Dental products *Dental products*	Restorative materials, dental *Restorative Materials, Dental*	16-188
	Composite restorative material, dental, heat-cured *Composite Restorative Materials, Dental, Heat-Cured*	16-726

Where applicable, changes to the scope of certificates are reported to the German Medical Devices Information and Database System (DMIDS) in accordance with the transitional provisions under Section 96 of the MPDG.
Where applicable, changes to the scope of certificates are reported to the "German Medical Devices Information and Database System" (DMIDS), in accordance with the transitional provisions under Section 96 of the MPDG.

p.p.

Digitally signed by Breder Jörg
Date: 2022.04.08 13:02:25 +02'00'

TÜV NORD CERT GmbH
Certification Body for Medical Devices
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