

EC-Certificate / EC-Certificate

acc. 93/42/EEC Annex V / acc. 93/42/EEC Annex V

This certifies, that the company / This certifies, that the company

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

for the products / the category: List of products see Annex 1
for the products / product category: List of products see annex 1

Dental products
Dental products

applies a quality assurance system for the manufacture of the products mentioned in accordance with Annex V of Directive 93/42/EEC. Compliance with the requirements was verified in an audit.
In addition to the CE marking, the identification number of the notified body must be affixed. The validity of this certificate is based on the maintenance of the quality system in conformity with the requirements of the Directive and its surveillance by the Notified Body in accordance with Annex V, section 4.
transferable under certain circumstances.

has established a quality system for production acc. to the requirements of Annex V of the directive 93/42/EEC. Conformity with the requirements was proved within an audit. In addition to the CE-marking the identification number of the Notified Body has to be affixed. The validity of this certificate is based on the maintenance of the quality system in accordance with the requirements of the directive and its surveillance by the Notified Body according Annex V section 4. The certificate may not be transferred under any circumstances.

Reg. no. / Reg.-No. 44 235 202395
Report No. / Report No. 3528 0833



Gültigkeit / Validity von
/ from 2021-01-19 bis /
until 2023-09-23
Edition 1

Certification body for medical devices
Certification body for medical devices

Essen, 2021-01-19

TÜV NORD GmbH

Langemarckstraße 20

45141 Essen

www.tuev-nord-cert.de

medical@tuev-nord.de Notified Body ID No. 0044 / Notified Body ID. No. 0044



Benannt durch / Designated by
Zentralstelle der Länder @
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS -236.10.16

ANNEX

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Reg. No. / Reg. No. 44 235 202395

| Products of class 11a <i>Products of class 11a</i> | Type e Type | UMDNS |
|---|--|--------|
| Dental products <i>Dental</i> | Restoration material, dental <i>Restorative Materials, Dental</i> | 16-188 |
| | Composite Restorative Material, Dental, <i>Heat-Cured Composite Restorative Materials, Dental, Heat-Cured</i> | 16-726 |

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von / from 2021-01-19
Edition 1

Essen, 2021-01-19

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*



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for health protection @ for
medicinal products and
Medizinprodukten
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