# EU Quality Management System Certificate

Pursuant to Regulation (EU) 2017/745 on Medical Devices,
Annex IX, Chapters I and III

The Notified Body of TÜV NORD CERT GmbH certifies that the manufacturer

## SCHEU-DENTAL GmbH
## Am Burgberg 20
## 58642 Iserlohn
## Germany

has established, documented and implemented a quality management system in accordance with Article 10, paragraph 9 of Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The conformity assessment has been carried out and successfully completed in accordance with Annex IX, Chapters I and III. The result of the assessment, references to investigations carried out, relevant common specifications and test reports are summarised in the report mentioned below. The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The validity of this certificate is based on the maintenance of the quality management system in accordance with the requirements of the Regulation and its regular surveillance by the Notified Body in accordance with Annex IX, Chapter I, Section 3. For devices of class IIb and IIa the surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

In addition to the CE marking, the identification number of the Notified Body must be affixed to the devices.

For the placing on the market of class III and class IIb implantable devices an additional EU technical documentation assessment certificate according to Annex IX, Chapter II is required.

| | |
|---|---|
| **Single Registration Number of the Manufacturer (SRN):** | DE-MF-000000022 |
| **Authorised Representative:** | see Section 1 |
| **Limitations and Conditions:** | see Section 2 |
| **List of Products, Risk Classification and Details:** | see Section 3 |
| **Certificate History:** | see Section 4 |

| | | | |
|---|---|---|---|
| Certificate number: | 44 911 221723 | Valid from: | 2025-03-26 |
| Certification decision report No.: | 3536 6924 | Valid until: | 2030-03-25 |
| | | First issued: | 2025-03-26 |
| | | Issue date: | 2025-03-26 |
| | | Edition: | 1 |

B. Hoy

TÜV NORD CERT GmbH is a Notified Body with identification number 0044

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Certificate number: 44 911 221723

## Section 1, Authorised Representative

| | |
|---|---|
| **Company name:** | **N/A** |
| **Street, No.:** | -- |
| **Postal Code, City:** | -- |
| **Country:** | -- |
| **Single Registration Number:** | -- |

## Section 2, Limitations and Conditions

| | |
|---|---|
| **The validity of this Certificate depends on:** | T**he elimination of non-conformities according to the CAPA plan**. |
| **and the following conditions:** | None |
| **and / or is limited to the following:** | N/A |

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Section 3, List of Products, Risk Classification and Details

**CLASS IIA**

| | |
|---|---|
| **Category of device (MDx Code):** | **MDN 1209,**<br>Non-active non-implantable dental materials |
| TD assessment report no.: | 3536 2134 |
| Basic UDI-DI: | Product name: |
| ++J018ORTHODONTICSHEATHWQ | Activator tubes / Aktivatorröhrchen |
| ++J018FOILBIOCRYLC9S | BIOCRYL C |
| ++J018ORTHORESINBIOCRYL5N | BIOCRYL-RESIN |
| ++J018FOILBIOPLASTAW | BIOPLAST |
| ++J018ORTHODONTICBARSLV | Bars / Bügel |
| ++J018FOILCA2B | CA Foil / CA Folie |
| ++J018FOILCAPROE9 | CA Pro |
| ++J018FOILCARETENTIONFA | CA Retention foil / CA Retentionsfolie |
| ++J018ORTHODONTICWIRESDW | CHROMIUM |
| ++J018FOILCOPYPLASTMM | COPYPLAST C |
| ++J018FOILDURANHM | DURAN |
| ++J018FOILDURASOFTH2 | DURASOFT |
| ++J018ORTHORESINDURASPLBH | DURASPLINT |
| ++J018ORTHODONTICSCREWSZF | Palatal expansion screws / GNE-Schrauben |
| ++J018FOILIMPRELONSKS | IMPRELON S |
| ++J018ORTHODONTICCLASPSTU | Clasps orthodontics / Klammern_KFO |
| ++J018ORTHODONTICCLASPSTU | Clasps / Klammern_Klammertechnik |
| ++J018ORTHODONTICSHEATHWQ | Lingual/palatal sheath / Lingual-/Palatinalschloss |
| ++J018ORTHODONTICWIRESDW | MENZANIUM |
| ++J018ORTHODONTICARCHM8 | Palatal bar / Palatinalbügel |
| ++J018ORTHODONTICARCHM8 | Quad Helix |
| ++J018HINGES2P | Hinges / Scharniere |
| ++J018ORTHORESINSTEADYLC | STEADY-RESIN |
| ++J018TELESCOPES4P | Telescopes / Teleskope |
| ++J018FOILUNIQBA | UNIQ |

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Section 4, Certificate History

| Edition | Date | Action leading to revision | Report reference |
|---|---|---|---|
| 1 | 2025-03-26 | Initial certification | ZA 3536 6924 |

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TÜV®

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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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