

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60135991 0001

Report No.: 21208078 021

Manufacturer: Gebr. Brasseler GmbH & Co. KG
Trophagener Weg 25
32657 Lemgo
Deutschland

Products: Non-active medical devices

(see attachment for products included)

Replaces Approval, Registration-No.: HD 60091372 0001

Expiry Date: 2024-01-19

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2019-01-20

Date: 2019-01-17

Notified Body

Dr. K. Kluge



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60135991 0001
Report No.: 21208078 021

Manufacturer: Gebr. Brasseler GmbH & Co. KG
Trophagener Weg 25
32657 Lemgo
Deutschland

Products included:

- Rotary and oscillating instruments for dentistry
- Rotary instruments and saw blades for orthopedics, dermatology, surgery and ophthalmology
- Posts, screws and prefabricated elements as well as auxiliary parts for the restoration of teeth
- Composite systems for root post cementation and core build-up
- Instruments for podiatry
- Agents for the cleaning and disinfection of medical devices
- Pins and screws for use in orthopedics
- Rotary endodontic instruments
- Filling material for root canals and paper points for drying the root canal
- Dental hand pieces and contra-angles

Date: 2019-01-17

Notified Body



Dr. K. Kluge



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60135991 0001
Report No.: 21208078 021

Manufacturer: Gebr. Brasseler GmbH & Co. KG
Trophagener Weg 25
32657 Lemgo
Deutschland

For the following devices the scope covers only
the aspects of the manufacture concerned with
the securing and maintaining sterile conditions:

- Manual instruments and tools for use in dentistry

Notified Body



Date: 2019-01-17

TÜV Rheinland LGA Products GmbH • 51105 Köln

Gebr. Brasseler GmbH & Co. KG
Trophagener Weg 25
32657 Lemgo
Germany

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date May 16, 2024

Notified Body Confirmation Letter

Reference: BRASS_PLA0_HZ_2024-05-07, order #1162077

To whom it may concern,

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.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, 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:

Gebr. Brasseler GmbH & Co. KG
Trophagener Weg 25
32657 Lemgo
Germany
SRN Number: DE-MF-000006446

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance 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 May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either 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 March 20, 2023 for the relevant devices.

TÜV Rheinland
LGA Products GmbH

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51105 Köln
Germany

Headquarter

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Board of Management

Dipl.-Ing.
Thomas Weigand, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Nuremberg HRB 26013
VAT No.: DE 811835490

Chairman of the
Supervisory Board

Dr.-Ing. Michael Fübi

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:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 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)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 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)

On behalf of the Notified Body



Certification body

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
1.	++E2265330333U	IIa	N/A	HD 60135991 0001 #0197
2.	++E226533093GPLFR	IIa	N/A	HD 60135991 0001 #0197
3.	++E226533093SPLHM	IIa	N/A	HD 60135991 0001 #0197
4.	++E2265331554B	IIa	N/A	HD 60135991 0001 #0197
5.	++E226533155SUL3	IIa	N/A	HD 60135991 0001 #0197
6.	++E22653303846	IIa	N/A	HD 60135991 0001 #0197
7.	++E2265330513W	IIa	N/A	HD 60135991 0001 #0197
8.	++E226533031CPL	IIa	N/A	HD 60135991 0001 #0197

	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
9.	++E226533031CSH2	IIa	N/A	HD 60135991 0001 #0197
10.	++E226533031DPN	IIa	N/A	HD 60135991 0001 #0197
11.	++E226533031DSH5	IIa	N/A	HD 60135991 0001 #0197
12.	++E226533031StLA	IIa	N/A	HD 60135991 0001 #0197
13.	++E226533031StSJG	IIa	N/A	HD 60135991 0001 #0197
14.	++E226533031TDHP	IIa	N/A	HD 60135991 0001 #0197
15.	++E226533031TDSEL	IIa	N/A	HD 60135991 0001 #0197
16.	++E226533032CSH7	IIa	N/A	HD 60135991 0001 #0197
17.	++E226533032DSHA	IIa	N/A	HD 60135991 0001 #0197
18.	++E226533032StSJP	IIa	N/A	HD 60135991 0001 #0197
19.	++E226533032TDSET	IIa	N/A	HD 60135991 0001 #0197
20.	++E2265323864R	Ir	N/A	HD 60135991 0001 #0197
21.	++E226532386SS6	Is	N/A	HD 60135991 0001 #0197
22.	++E2265331734D	Is	N/A	HD 60135991 0001 #0197
23.	++E2265326244J	Is	N/A	HD 60135991 0001 #0197
24.	++E2265326244J	Ir	N/A	HD 60135991 0001 #0197
25.	++E2265331564D	IIa	N/A	HD 60135991 0001 #0197
26.	++E2265327721SJG	IIa	N/A	HD 60135991 0001 #0197
27.	++E2265327721QF	IIa	N/A	HD 60135991 0001 #0197

	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
28.	++E2265327722SUEV	IIa	N/A	HD 60135991 0001 #0197
29.	++E2265327722SJK	IIa	N/A	HD 60135991 0001 #0197
30.	++E2265327722SSUDM	IIa	N/A	HD 60135991 0001 #0197
31.	++E2265327723SSUDU	IIa	N/A	HD 60135991 0001 #0197
32.	++E2265327724SSUE3	IIa	N/A	HD 60135991 0001 #0197
33.	++E2265327724SJR	IIa	N/A	HD 60135991 0001 #0197
34.	++E2265327725SJU	IIa	N/A	HD 60135991 0001 #0197
35.	++E2265327725QJP	IIa	N/A	HD 60135991 0001 #0197
36.	++E2265327723SJM	IIa	N/A	HD 60135991 0001 #0197
37.	++E226532797CSA	IIa	N/A	HD 60135991 0001 #0197
38.	++E226532797CSMA	IIa	N/A	HD 60135991 0001 #0197
39.	++E226532797CSUK6	IIa	N/A	HD 60135991 0001 #0197
40.	++E226532797DSC	IIa	N/A	HD 60135991 0001 #0197
41.	++E226532797DSMD	IIa	N/A	HD 60135991 0001 #0197
42.	++E226532810CQL	IIa	N/A	HD 60135991 0001 #0197
43.	++E226532810CDHU	IIa	N/A	HD 60135991 0001 #0197
44.	++E226532810CSDR	IIa	N/A	HD 60135991 0001 #0197
45.	++E226532810CSJS	IIa	N/A	HD 60135991 0001 #0197
46.	++E226532810DQN	IIa	N/A	HD 60135991 0001 #0197

	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
47.	++E226532810DSJV	IIa	N/A	HD 60135991 0001 #0197
48.	++E226532810StN2	IIa	N/A	HD 60135991 0001 #0197
49.	++E226532810StSLA	IIa	N/A	HD 60135991 0001 #0197
50.	++E2265328134P	IIa	N/A	HD 60135991 0001 #0197
51.	++E22653285353	IIa	N/A	HD 60135991 0001 #0197
52.	++E226532853SSH	IIa	N/A	HD 60135991 0001 #0197
53.	++E22653285455	IIa	N/A	HD 60135991 0001 #0197
54.	++E226532854SSL	IIa	N/A	HD 60135991 0001 #0197
55.	++E22653285557	IIa	N/A	HD 60135991 0001 #0197
56.	++E226532855SSP	IIa	N/A	HD 60135991 0001 #0197
57.	++E22653284758	IIa	N/A	HD 60135991 0001 #0197
58.	++E22653285659	IIa	N/A	HD 60135991 0001 #0197
59.	++E226532856SSS	IIa	N/A	HD 60135991 0001 #0197
60.	++E2265328575B	IIa	N/A	HD 60135991 0001 #0197
61.	++E22653288056	IIa	N/A	HD 60135991 0001 #0197
62.	++E226532880SSP	IIa	N/A	HD 60135991 0001 #0197
63.	++E22653286152	IIa	N/A	HD 60135991 0001 #0197
64.	++E226532861SSG	IIa	N/A	HD 60135991 0001 #0197
65.	++E22653286254	IIa	N/A	HD 60135991 0001 #0197

	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
66.	++E226532862SSK	IIa	N/A	HD 60135991 0001 #0197
67.	++E226532867CSLY	IIa	N/A	HD 60135991 0001 #0197
68.	++E226532867DS4	IIa	N/A	HD 60135991 0001 #0197
69.	++E226532867DSM3	IIa	N/A	HD 60135991 0001 #0197
70.	++E226532867StQ8	IIa	N/A	HD 60135991 0001 #0197
71.	++E226532867StSPJ	IIa	N/A	HD 60135991 0001 #0197
72.	++E22653304747	IIa	N/A	HD 60135991 0001 #0197
73.	++E226533047SRB	IIa	N/A	HD 60135991 0001 #0197
74.	++E22653304849	IIa	N/A	HD 60135991 0001 #0197
75.	++E226533048SRE	IIa	N/A	HD 60135991 0001 #0197
76.	++E2265330494B	IIa	N/A	HD 60135991 0001 #0197
77.	++E226533049SRH	IIa	N/A	HD 60135991 0001 #0197
78.	++E2265330503U	IIa	N/A	HD 60135991 0001 #0197
79.	++E226533050SQT	IIa	N/A	HD 60135991 0001 #0197
80.	++E2265330173W	IIa	N/A	HD 60135991 0001 #0197
81.	++E226533017SQU	IIa	N/A	HD 60135991 0001 #0197
82.	++E2265330263X	IIa	N/A	HD 60135991 0001 #0197
83.	++E2265330694H	IIa	N/A	HD 60135991 0001 #0197
84.	++E2265330273Z	IIa	N/A	HD 60135991 0001 #0197

	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
85.	++E2265330303N	IIa	N/A	HD 60135991 0001 #0197
86.	++E22653305444	IIa	N/A	HD 60135991 0001 #0197
87.	++E2265330183Y	IIa	N/A	HD 60135991 0001 #0197
88.	++E226533018SQX	IIa	N/A	HD 60135991 0001 #0197
89.	++E22653302843	IIa	N/A	HD 60135991 0001 #0197
90.	++E226533028SR4	IIa	N/A	HD 60135991 0001 #0197
91.	++E226533071DQA	IIa	N/A	HD 60135991 0001 #0197
92.	++E226533071DSHZ	IIa	N/A	HD 60135991 0001 #0197
93.	++E226533071StM6	IIa	N/A	HD 60135991 0001 #0197
94.	++E226533071StSKU	IIa	N/A	HD 60135991 0001 #0197
95.	++E2265330681KSCH	IIa	N/A	HD 60135991 0001 #0197
96.	++E2265330681StEZ	IIa	N/A	HD 60135991 0001 #0197
97.	++E2265330681StSEF	IIa	N/A	HD 60135991 0001 #0197
98.	++E2265330682PQ	IIa	N/A	HD 60135991 0001 #0197
99.	++E2265330683PS	IIa	N/A	HD 60135991 0001 #0197
100.	++E2265330701P3	IIa	N/A	HD 60135991 0001 #0197
101.	++E2265330701SG6	IIa	N/A	HD 60135991 0001 #0197
102.	++E2265330702P5	IIa	N/A	HD 60135991 0001 #0197
103.	++E2265330702SG9	IIa	N/A	HD 60135991 0001 #0197

	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
104.	++E2265330703P7	IIa	N/A	HD 60135991 0001 #0197
105.	++E2265330703SGC	IIa	N/A	HD 60135991 0001 #0197
106.	++E226533078PSUJE	IIa	N/A	HD 60135991 0001 #0197
107.	++E226533078SDKK	IIa	N/A	HD 60135991 0001 #0197
108.	++E226533078SStLH	IIa	N/A	HD 60135991 0001 #0197
109.	++E226533078SStSN3	IIa	N/A	HD 60135991 0001 #0197
110.	++E226533078USStLT	IIa	N/A	HD 60135991 0001 #0197
111.	++E226533079DR2	IIa	N/A	HD 60135991 0001 #0197
112.	++E226533079DSK9	IIa	N/A	HD 60135991 0001 #0197
113.	++E226533079CQY	IIa	N/A	HD 60135991 0001 #0197
114.	++E226533079CSK6	IIa	N/A	HD 60135991 0001 #0197
115.	++E226533079CZKL	IIa	N/A	HD 60135991 0001 #0197
116.	++E226533079CZSH5	IIa	N/A	HD 60135991 0001 #0197
117.	++E226533079KRG	IIa	N/A	HD 60135991 0001 #0197
118.	++E226533079KSKW	IIa	N/A	HD 60135991 0001 #0197
119.	++E226533079StNE	IIa	N/A	HD 60135991 0001 #0197
120.	++E22653308045	IIa	N/A	HD 60135991 0001 #0197
121.	++E2265330811PB	IIa	N/A	HD 60135991 0001 #0197
122.	++E2265330811SGJ	IIa	N/A	HD 60135991 0001 #0197

	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
123.	++E2265330812PD	IIa	N/A	HD 60135991 0001 #0197
124.	++E226533108DQ3	IIa	N/A	HD 60135991 0001 #0197
125.	++E226533108DSHW	IIa	N/A	HD 60135991 0001 #0197
126.	++E226533108StM3	IIa	N/A	HD 60135991 0001 #0197
127.	++E226533108StSKD	IIa	N/A	HD 60135991 0001 #0197
128.	++E2265331023N	IIa	N/A	HD 60135991 0001 #0197
129.	++E226533102SQF	IIa	N/A	HD 60135991 0001 #0197
130.	++E2265331243Y	IIa	N/A	HD 60135991 0001 #0197
131.	++E226533124SQX	IIa	N/A	HD 60135991 0001 #0197
132.	++E226533124SSUGP	IIa	N/A	HD 60135991 0001 #0197
133.	++E226533124SUK9	IIa	N/A	HD 60135991 0001 #0197
134.	++E22653312746	IIa	N/A	HD 60135991 0001 #0197
135.	++E226533116CPY	IIa	N/A	HD 60135991 0001 #0197
136.	++E226533116DQ2	IIa	N/A	HD 60135991 0001 #0197
137.	++E226533116KQG	IIa	N/A	HD 60135991 0001 #0197
138.	++E226533116StLY	IIa	N/A	HD 60135991 0001 #0197
139.	++E2265330343W	IIa	N/A	HD 60135991 0001 #0197
140.	++E226533034SQV	IIa	N/A	HD 60135991 0001 #0197
141.	++E22653315347	IIa	N/A	HD 60135991 0001 #0197

	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
142.	++E226533153SRB	IIa	N/A	HD 60135991 0001 #0197
143.	++E22653314344	IIa	N/A	HD 60135991 0001 #0197
144.	++E226533143SR6	IIa	N/A	HD 60135991 0001 #0197
145.	++E2265328661QV	IIa	N/A	HD 60135991 0001 #0197
146.	++E2265328661AJ4	IIa	N/A	HD 60135991 0001 #0197
147.	++E2265328661CJ8	IIa	N/A	HD 60135991 0001 #0197
148.	++E2265328662QX	IIa	N/A	HD 60135991 0001 #0197
149.	++E2265328663QZ	IIa	N/A	HD 60135991 0001 #0197
150.	++E2265328663CJE	IIa	N/A	HD 60135991 0001 #0197
151.	++E2265328665R5	IIa	N/A	HD 60135991 0001 #0197

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
2024/05/16	BRASS_CL_607_2024-05-16.pdf	Initial issue
YYYY/MM/DD	XXXXXXXXXX	Addition of device XYZ to the list
YYYY/MM/DD	XXXXXXXXXX	Removal of device XYZ to the list

Manufacturer's Declaration

[1/15]



In relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*¹
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Gebr. Brasseler GmbH & Co. KG
Manufacturer address and contact details	Trophagener Weg 25 32657 Lemgo Germany
Single Registration Number (SRN)	DE-MF-000006446

Notified body name	TÜV Rheinland LGA Products GmbH
Notified body number	0197
Directive Certificate number(s) to which this confirmation is made	HD 60135991 0001
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	January 19, 2024
End date of extended validity/transition period	December 31, 2028

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*²

¹ The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

² The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body



• the listed **devices** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service, namely by fulfilling the following conditions:

➤ **Directive Certificate** as listed above

- Directive Certificate covering the listed devices was issued after 25 May 2017, was valid on 26 May 2021 and has not been withdrawn afterwards.

The Directive Certificate expires after 20 March 2023:

Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made by us to a notified body for the devices listed in the attached schedule or their substitutes and signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR.

➤ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made by us to a notified body for the devices listed in the attached schedule or their substitutes and signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR.

➤ **Quality Management System (QMS)**

A QMS in accordance with Article 10(9) MDR is in place.

➤ **Devices as listed in the attached schedule**

- The devices continue to comply with the MDD.
- There are no significant changes in the design and intended purpose.
- The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Manufacturer´s Declaration

[3/15]



Signed for and on behalf of the manufacturer:

Gebr. Brasseler GmbH & Co. KG
Trophagener Weg 25
32657 Lemgo

i. V. 
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Date 21.05.2024

Manufacturer's Declaration

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Nr	Basic UDI-DI	Terminology of Basic-UDI-DI	EMDN Code	Product group according to the certificate MDD	TD Number (of legacy device)	UMDNS Code
1	++E2265330333U	Screwdriver surgical	L26	Rotary instruments and saw blades for orthopaedics, dermatology, surgery and ophthalmology	532463	13-517
2	++E2265330936PLFR	Root posts for the indirect build-up GPL_Gold Platinum	Q010102	Posts, screws and prefabricated elements as well as auxiliary parts for the restoration of teeth	150/647	16-202
3	++E2265330935PLHM	Root posts for the indirect build-up SPL_silver palladium	Q010102	Posts, screws and prefabricated elements as well as auxiliary parts for the restoration of teeth	150/647	16-202
4	++E2265331554B	Polishers	Q010199	Rotary and oscillating instruments for dentistry	533155	16-412
5	++E226533155SUL3	Polishers single use	Q010502	Rotary and oscillating instruments for dentistry	533155	16-412
6	++E22653303846	Instruments for rust ring removal single use	Q020202	Rotary and oscillating instruments for dentistry	531763	16-413
7	++E2265330513W	Rotary steel instruments for cavity preparation and work on fillings	Q010199	Rotary and oscillating instruments for dentistry	101/349 100/008	16-669
8	++E226533031CPL	Rotary instruments KM C_Carbide	L090999	Rotary instruments and saw blades for orthopaedics, dermatology, surgery and ophthalmology	101/286	17-761
9	++E226533031CSH2	Rotary instruments KM C_Carbide S_Steril	L090999	Rotary instruments and saw blades for orthopaedics, dermatology, surgery and ophthalmology	530383	17-761
10	++E226533031DPN	Rotary instruments KM D_Diamond	L090999	Rotary instruments and saw blades for orthopaedics, dermatology, surgery and ophthalmology	101/286	17-761

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11	++E226533031DSH5	Rotary instruments KM D_Diamond_Sterile	L090999	Rotary instruments and saw blades for orthopaedics, dermatology, surgery and ophthalmology	530383	17-761
12	++E226533031STLA	Rotary instruments KM St_Steel	L090999	Rotary instruments and saw blades for orthopaedics, dermatology, surgery and ophthalmology	101/286	17-761
13	++E226533031ST5JG	Rotary instruments KM St_Steel S_Sterile	L090999	Rotary instruments and saw blades for orthopaedics, dermatology, surgery and ophthalmology	530383	17-761
14	++E226533031TDHP	Rotary instruments KM TD_Twist Drill	L090999	Rotary instruments and saw blades for orthopaedics, dermatology, surgery and ophthalmology	101/286	17-761
15	++E226533031TDSEL	Rotary instruments KM TD_Twist Drill S_Sterile	L090999	Rotary instruments and saw blades for orthopaedics, dermatology, surgery and ophthalmology	530383	17-761
16	++E226533032CSH7	Rotary single-use instruments KM_Carbide_Sterile	L090999	Rotary instruments and saw blades for orthopaedics, dermatology, surgery and ophthalmology	530383	17-761
17	++E226533032DSHA	Rotary single-use instruments KM_Diamond_Sterile	L090999	Rotary instruments and saw blades for orthopaedics, dermatology, surgery and ophthalmology	530383	17-761
18	++E226533032ST5JP	Rotary single-use instruments KM_Steel_Sterile	L090999	Rotary instruments and saw blades for orthopaedics, dermatology, surgery and ophthalmology	530383	17-761
19	++E226533032TDSET	Rotary single-use instruments KM_Twist Drill_Sterile	L090999	Rotary instruments and saw blades for orthopaedics, dermatology, surgery and ophthalmology	530383	17-761
20	++E2265323864R	Dental hand instruments for root post systems	Q010199	Rotary and oscillating instruments for dentistry	532386	16-662
21	++E226532386SS6	Dental hand instruments for root post systems - STERILE-	Q010199	Rotary and oscillating instruments for dentistry	532386	16-662
22	++E2265331734D	Manual accessories endodontics	Q010199	Rotary and oscillating instruments for dentistry	532384	17-992
23	++E2265326244J	Endodontic instruments for single use - STERILE	L159004	Rotary endodontic instruments	532624	16-662
24	++E2265326244J	Endodontic instruments for single use - STERILE	L159004	Rotary endodontic instruments	532624	16-662

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25	++E2265331564D	Nerve Broaches Single use	Q010507	Rotary endodontic instruments	532625	16-662
26	++E2265327721S1G	Root canal instruments nickel titanium 1S_Opener_Sterile	L159004	Rotary endodontic instruments	532772	16-662
27	++E2265327721QF	Root canal instruments nickel titanium 1_Opener	L159004	Rotary endodontic instruments	532772	16-662
28	++E2265327722S1EUV	Root canal instruments nickel titanium 2SU_Pathglider_Single Use	Q010507	Rotary endodontic instruments	532772	16-662
29	++E2265327722S1JK	Root canal instruments nickel titanium 2S_Pathglider_Sterile	L159004	Rotary endodontic instruments	532772	16-662
30	++E2265327722SSUDM	Root canal instruments nickel titanium 2SSU_Pathglider_Sterile_Single Use	Q010507	Rotary endodontic instruments	532772	16-662
31	++E2265327723SSUDU	Root canal instruments nickel titanium 3SSU_mechanical Processing_Sterile_Single Use	Q010507	Rotary endodontic instruments	532772	16-662
32	++E2265327724SSUE3	Root canal instruments nickel titanium 4SSU_Revision_Sterile_Single Use	Q010507	Rotary endodontic instruments	532772	16-662
33	++E2265327724S1JR	Root canal instruments nickel titanium 4S_Revision_Sterile	L159004	Rotary endodontic instruments	532772	16-662
34	++E2265327725S1JU	Root canal instruments nickel titanium 5S_Guttapercha Remover_Sterile	L159004	Rotary endodontic instruments	532772	16-662
35	++E2265327725QP	Root canal instruments nickel titanium 5_Guttapercha Remover	L159004	Rotary endodontic instruments	532772	16-662
36	++E2265327723S1JN	Root canal instruments nickel titanium 3S_mechanical Processing_Sterile	Q010507	Rotary endodontic instruments	532772	16-662

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37	++E226532797CSA	Crown Cutter C_Carbide	Q010199	Rotary and oscillating instruments for dentistry	532797	16-668
38	++E226532797CSMA	Crown Cutter CS_Carbide Sterile	Q010199	Rotary and oscillating instruments for dentistry	532797	16-668
39	++E226532797CSUK6	Crown Cutter CSU_Carbide Single Use	Q010501	Rotary and oscillating instruments for dentistry	532797	16-668
40	++E226532797DSC	Crown Cutter D_Diamond	Q010199	Rotary and oscillating instruments for dentistry	532797	16-670
41	++E226532797DSMD	Crown Cutter DS_Diamond Sterile	Q010199	Rotary and oscillating instruments for dentistry	532797	16-670
42	++E226532810CQL	Endodontic Instruments for Access Cavity C_Carbide	Q010199	Rotary and oscillating instruments for dentistry	532810	16-668
43	++E226532810CDHU	Endodontic Instruments for Access Cavity CD_Cardia	Q010199	Rotary and oscillating instruments for dentistry	532810	16-668
44	++E226532810CDSDR	Endodontic Instruments for Access Cavity CDS_Carida Sterile	Q010199	Rotary and oscillating instruments for dentistry	532810	16-668
45	++E226532810CSJS	Endodontic Instruments for Access Cavity CS_Carbide Sterile	Q010199	Rotary and oscillating instruments for dentistry	532810	16-668
46	++E226532810DQN	Endodontic Instruments for Access Cavity D_Diamond	Q010199	Rotary and oscillating instruments for dentistry	532810	16-670
47	++E226532810DSJV	Endodontic Instruments for Access Cavity DS_Diamond Sterile	Q010199	Rotary and oscillating instruments for dentistry	532810	16-670
48	++E226532810StN2	Endodontic Instruments for Access Cavity St_Steel	Q010199	Rotary and oscillating instruments for dentistry	532810	16-669
49	++E226532810StSLA	Endodontic Instruments for Access Cavity StS_Steel Sterile	Q010199	Rotary and oscillating instruments for dentistry	532810	16-669

Manufacturer's Declaration



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50	++E2265328134P	Instruments for foot surgery	V0199	Rotary instruments and saw blades for orthopaedics, dermatology, surgery and ophthalmology	532813	17-761
51	++E22653285353	Cavity preparation rotating diamond	Q010199	Rotary and oscillating instruments for dentistry	532853	16-670
52	++E226532853SSH	Cavity preparation rotating diamond S_Sterile	Q010199	Rotary and oscillating instruments for dentistry	532853	16-670
53	++E22653285455	Cavity preparation rotating carbide	Q010199	Rotary and oscillating instruments for dentistry	532854	16-668
54	++E226532854SSL	Cavity preparation rotating carbide S_Sterile	Q010199	Rotary and oscillating instruments for dentistry	532854	16-668
55	++E22653285557	Ceramic burs for dentin caries excavation	Q010199	Rotary and oscillating instruments for dentistry	532855	10-521
56	++E226532855SSP	Ceramic burs for dentin caries excavation S_Sterile	Q010199	Rotary and oscillating instruments for dentistry	532855	10-521
57	++E22653284758	Cavity preparation rotating plastics	Q010199	Rotary and oscillating instruments for dentistry	532847	10-521
58	++E22653285659	Craniotome	L090999	Rotary instruments and saw blades for orthopaedics, dermatology, surgery and ophthalmology	532856	17-761
59	++E226532856SSS	Craniotome	L090999	Rotary instruments and saw blades for orthopaedics, dermatology, surgery and ophthalmology	532856	17-761
60	++E2265328575B	Rasps single-use	V0199	Rotary instruments and saw blades for orthopaedics, dermatology, surgery and ophthalmology	532857	15-244
61	++E22653288056	Rasps	L090999	Rotary instruments and saw blades for orthopaedics, dermatology, surgery and ophthalmology	532880	15-244
62	++E226532880SSP	Rasps S_Sterile	L090999	Rotary instruments and saw blades for orthopaedics, dermatology, surgery and ophthalmology	532880	15-244

Manufacturer's Declaration



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63	++E22653286152	Crown preparation rotating diamond	Q010199	Rotary and oscillating instruments for dentistry	532861	16-670
64	++E226532861SSG	Crown preparation rotating diamond S_Sterile	Q010199	Rotary and oscillating instruments for dentistry	532861	16-670
65	++E22653286254	Crown preparation rotating carbide	Q010199	Rotary and oscillating instruments for dentistry	532862	16-668
66	++E226532862SSK	Crown preparation rotating carbide S_Sterile	Q010199	Rotary and oscillating instruments for dentistry	532862	16-668
67	++E226532867CSLY	Root canal post instruments CS_Carbide Sterile	Q010199	Rotary and oscillating instruments for dentistry	532867	16-668
68	++E226532867DS4	Root canal post instruments D_Diamond	Q010199	Rotary and oscillating instruments for dentistry	532867	16-670
69	++E226532867DSM3	Root canal post instruments DS_Diamond Sterile	Q010199	Rotary and oscillating instruments for dentistry	532867	16-670
70	++E226532867St08	Root canal post instruments St_Steel	Q010199	Rotary and oscillating instruments for dentistry	532867	16-669
71	++E226532867StSPJ	Root canal post instruments StS_Steel Sterile	Q010199	Rotary and oscillating instruments for dentistry	532867	16-669
72	++E22653304747	Preparation of restoration materials rotating diamond	Q010199	Rotary and oscillating instruments for dentistry	533047	16-670
73	++E226533047SRB	Preparation of restoration materials rotating diamond S_Sterile	Q010199	Rotary and oscillating instruments for dentistry	533047	16-670
74	++E22653304849	Preparation of restoration materials rotating carbide	Q010199	Rotary and oscillating instruments for dentistry	533048	16-668
75	++E226533048SRE	Preparation of restoration materials rotating carbide S_Sterile	Q010199	Rotary and oscillating instruments for dentistry	533048	16-668
76	++E2265330494B	Cavity and crown preparation rotating diamond	Q010199	Rotary and oscillating instruments for dentistry	533049	16-670
77	++E226533049SRH	Cavity and crown preparation rotating diamond S_Sterile	Q010199	Rotary and oscillating instruments for dentistry	533049	16-670
78	++E2265330503U	Crown preparation and preparation of restoration materials rotating diamond	Q010199	Rotary and oscillating instruments for dentistry	533050	16-670

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79	++E226533050SQT	Crown preparation and preparation of restoration materials rotating diamond S_Sterile	Q010199	Rotary and oscillating instruments for dentistry	533050	16-670
80	++E2265330173W	Saw Blades Sternum	L090999	Rotary instruments and saw blades for orthopaedics, dermatology, surgery and ophthalmology	533017	15-244
81	++E2265330175QU	Saw Blades Sternum S_Sterile	L090999	Rotary instruments and saw blades for orthopaedics, dermatology, surgery and ophthalmology	533017	15-244
82	++E2265330263X	Saw Blades Sternum Single Use	V0199	Rotary instruments and saw blades for orthopaedics, dermatology, surgery and ophthalmology	533026	15-244
83	++E2265330694H	Mandrels for grinding and polishing instruments	Q010199	Rotary and oscillating instruments for dentistry	533069	16-669
84	++E2265330273Z	Single-use bone saw blades	V0199	Rotary instruments and saw blades for orthopaedics, dermatology, surgery and ophthalmology	533027	15-244
85	++E2265330303N	Single-use saw blades for endoprosthetics	V0199	Rotary instruments and saw blades for orthopaedics, dermatology, surgery and ophthalmology	533030	15-244
86	++E22653305444	Shank extensions for dental implantology	Q010399	Rotary and oscillating instruments for dentistry	533054	16-669
87	++E2265330183Y	Bone saw blades	L090999	Rotary instruments and saw blades for orthopaedics, dermatology, surgery and ophthalmology	533018	15-244
88	++E2265330185QX	Bone saw blades S_Sterile	L090999	Rotary instruments and saw blades for orthopaedics, dermatology, surgery and ophthalmology	533018	15-244
89	++E22653302843	Saw blades for endoprosthetics	L090999	Rotary instruments and saw blades for orthopaedics, dermatology, surgery and ophthalmology	533028	15-244

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90	++E226533028SR4	Saw blades for endoprosthesis S_Sterile	L090999	Rotary instruments and saw blades for orthopaedics, dermatology, surgery and ophthalmology	533028	15-244
91	++E226533071DQA	Sonic tips for surgery D_Diamond	Q010399	Rotary and oscillating instruments for dentistry	533071	16-693
92	++E226533071DSHZ	Sonic tips for surgery D_Diamond; S_Sterile	Q010399	Rotary and oscillating instruments for dentistry	533071	16-693
93	++E226533071StM6	Sonic tips for surgery St_Steel	Q010399	Rotary and oscillating instruments for dentistry	533071	16-693
94	++E226533071StSKU	Sonic tips for surgery St_Steel; S_Sterile	Q010399	Rotary and oscillating instruments for dentistry	533071	16-693
95	++E2265330681KSCH	Instruments for implantology 1_Pilot drill for implantology; K_Ceramics; S_Sterile	Q010399	Rotary and oscillating instruments for dentistry	533068	10-521
96	++E2265330681StEZ	Instruments for implantology 1_Pilot drill for implantology; St_Steel	Q010399	Rotary and oscillating instruments for dentistry	533068	16-669
97	++E2265330681StSEF	Instruments for implantology 1_Pilot drill for implantology; St_Steel; S_Sterile	Q010399	Rotary and oscillating instruments for dentistry	533068	16-669
98	++E2265330682PQ	Instruments for implantology 2_Triangle drill	Q010399	Rotary and oscillating instruments for dentistry	533068	16-669
99	++E2265330683PS	Instruments for implantology 3_Shank extension	Q010399	Rotary and oscillating instruments for dentistry	533068	16-669
100	++E2265330701P3	Sonic Tips 1_Crown Preparation	Q010199	Rotary and oscillating instruments for dentistry	533070	16-693
101	++E2265330701SG6	Sonic Tips 1_Crown Preparation; S_Sterile	Q010199	Rotary and oscillating instruments for dentistry	533070	16-693
102	++E2265330702P5	Sonic Tips 2_Cavity Preparation	Q010199	Rotary and oscillating instruments for dentistry	533070	16-693
103	++E2265330702SG9	Sonic Tips 2_Cavity Preparation; S_Sterile	Q010199	Rotary and oscillating instruments for dentistry	533070	16-693
104	++E2265330703P7	Sonic Tips 3_Preparation of restoration materials	Q010199	Rotary and oscillating instruments for dentistry	533070	16-693

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105	++E2265330703SGC	Sonic Tips 3_Preparation of restoration materials; S_Sterile	Q010199	Rotary and oscillating instruments for dentistry	533070	16-693
106	++E226533078PSUJE	Sonic and ultrasonic instruments for prophylaxis and periodontal treatments P_PEEK; SU_Single Use	Q010199	Rotary and oscillating instruments for dentistry	533078	16-693
107	++E226533078SDKK	Sonic and ultrasonic instruments for prophylaxis and periodontal treatments S_Sonic; D_Diamond	Q010199	Rotary and oscillating instruments for dentistry	533078	16-693
108	++E226533078SSELH	Sonic and ultrasonic instruments for prophylaxis and periodontal treatments S_Sonic; St_Steel	Q010199	Rotary and oscillating instruments for dentistry	533078	16-693
109	++E226533078SSISN3	Sonic and ultrasonic instruments for prophylaxis and periodontal treatments S_Sonic; St_Steel; S_Sterile	Q010199	Rotary and oscillating instruments for dentistry	533078	16-693
110	++E226533078USTLT	Sonic and ultrasonic instruments for prophylaxis and periodontal treatments U_Ultrasonic	Q010199	Rotary and oscillating instruments for dentistry	533078	16-693
111	++E226533079DR2	Instruments for oral and maxillofacial surgery D_Diamond	Q010399	Rotary and oscillating instruments for dentistry	533079	11-341
112	++E226533079DSK9	Instruments for oral and maxillofacial surgery D_Diamond; S_Sterile	Q010399	Rotary and oscillating instruments for dentistry	533079	11-341
113	++E226533079CQY	Instruments for oral and maxillofacial surgery C_Carbide	Q010399	Rotary and oscillating instruments for dentistry	533079	11-341
114	++E226533079CSK6	Instruments for oral and maxillofacial surgery C_Carbide; S_Sterile	Q010399	Rotary and oscillating instruments for dentistry	533079	11-341
115	++E226533079CZKL	Instruments for oral and maxillofacial surgery C_Carbide; Z_ZRN	Q010399	Rotary and oscillating instruments for dentistry	533079	11-341

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116	++E226533079CZSH5	Instruments for oral and maxillofacial surgery C_Carbide; Z_ZRN; S_Sterile	Q010399	Rotary and oscillating instruments for dentistry	533079	11-341
117	++E226533079KRG	Instruments for oral and maxillofacial surgery K_Ceramic	Q010399	Rotary and oscillating instruments for dentistry	533079	11-341
118	++E226533079KSKW	Instruments for oral and maxillofacial surgery K_Ceramic; S_Sterile	Q010399	Rotary and oscillating instruments for dentistry	533079	11-341
119	++E226533079StNE	Instruments for oral and maxillofacial surgery St_Steel	Q010399	Rotary and oscillating instruments for dentistry	533079	11-341
120	++E22653308045	Diamond discs for oral surgery	Q010399	Rotary and oscillating instruments for dentistry	533080	11-282
121	++E2265330811PB	Trepan burs and bone chip extractors 1_Trepan burs for bone cylinder	Q010399	Rotary and oscillating instruments for dentistry	533081	11-341
122	++E2265330811SGJ	Trepan burs and bone chip extractors 1_Trepan burs for bone cylinder; S_Sterile	Q010399	Rotary and oscillating instruments for dentistry	533081	11-341
123	++E2265330812PD	Trepan burs and bone chip extractors 2_bone chip extractors	Q010399	Rotary and oscillating instruments for dentistry	533081	11-341
124	++E226533108DQ3	Instruments for removing plaque and for root planning D_Diamond	Q010199	Rotary and oscillating instruments for dentistry	533108	16-670
125	++E226533108DSHW	Instruments for removing plaque and for root planning D_Diamond; S_Sterile	Q010199	Rotary and oscillating instruments for dentistry	533108	16-670
126	++E226533108StM3	Instruments for removing plaque and for root planning St_Steel	Q010199	Rotary and oscillating instruments for dentistry	533108	16-669
127	++E226533108StSKD	Instruments for removing plaque and for root planning St_Steel; S_Sterile	Q010199	Rotary and oscillating instruments for dentistry	533108	16-669
128	++E2265331023N	Instruments for implantoplasty	Q010199	Rotary and oscillating instruments for dentistry	533102	16-668

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129	++E226533102SQF	Instruments for implantoplasty S_Sterile	Q010199	Rotary and oscillating instruments for dentistry	533102	16-668
130	++E2265331243Y	Instruments for fragment treatment in the root canal	Q010199	Rotary and oscillating instruments for dentistry	533124	16-411
131	++E226533124SQX	Instruments for fragment treatment in the root canal S_Steril	Q010199	Rotary and oscillating instruments for dentistry	533124	16-411
132	++E226533124SSUGP	Instruments for fragment treatment in the root canal S_Steril SU_Single use	Q010507	Rotary endodontic instruments	533124	16-411
133	++E226533124SUK9	Instruments for fragment treatment in the root canal SU_Single use	Q010507	Rotary endodontic instruments	533124	16-411
134	++E22653312746	Diamond discs for the interproximal region	Q010199	Rotary and oscillating instruments for dentistry	533127	11-282
135	++E226533116CPY	instruments for podiatry C_Carbide	L2499	Instruments for podiatry	533116	11-177
136	++E226533116DQ2	instruments for podiatry D_Diamant	L2499	Instruments for podiatry	533116	11-177
137	++E226533116KQG	instruments for podiatry K_Ceramics	L2499	Instruments for podiatry	533116	11-177
138	++E226533116StLY	instruments for podiatry St_Steel	L2499	Instruments for podiatry	533116	11-177
139	++E2265330343W	Guide Pins/Screws Single use	V0199	Rotary instruments and saw blades for orthopaedics, dermatology, surgery and ophthalmology	533034	16-085
140	++E226533034SQV	Guide Pins/Screws Single use S_Sterile	V0199	Rotary instruments and saw blades for orthopaedics, dermatology, surgery and ophthalmology	533034	16-085
141	++E22653315347	Reciprocating instruments TD No 533153	Q010199	Rotary and oscillating instruments for dentistry	533153	16-693
142	++E226533153RB	Reciprocating instruments TD No 533153_Sterile	Q010199	Rotary and oscillating instruments for dentistry	533153	16-693

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143	++E22653314344	Sonic Tips for Endodontic Treatment	Q010199	Rotary and oscillating instruments for dentistry	533143	16-693
144	++E226533143SR6	Sonic Tips for Endodontic Treatment_Sterile	Q010199	Rotary and oscillating instruments for dentistry	533143	16-693
145	++E2265328661QV	Root posts TD No 532866 1_Titan	Q010102	Posts, screws and prefabricated elements as well as auxiliary parts for the restoration of teeth	532866	16-202
146	++E2265328661AJ4	Root posts TD No 532866 1_Titan;A_Active	Q010102	Posts, screws and prefabricated elements as well as auxiliary parts for the restoration of teeth	532866	16-202
147	++E2265328661CJ8	Root posts TD No 532866 1_Titan; C_Coated	Q010102	Posts, screws and prefabricated elements as well as auxiliary parts for the restoration of teeth	532866	16-202
148	++E2265328662QX	Root posts TD No 532866 2_Ceramics	Q010102	Posts, screws and prefabricated elements as well as auxiliary parts for the restoration of teeth	532866	16-202
149	++E2265328663QZ	Root posts TD No 532866 3_Composite	Q010102	Posts, screws and prefabricated elements as well as auxiliary parts for the restoration of teeth	532866	16-202
150	++E2265328663CJE	Root posts TD No 532866 3_Composite; C_Coated	Q010102	Posts, screws and prefabricated elements as well as auxiliary parts for the restoration of teeth	532866	16-202
151	++E2265328665R5	Root posts TD No 532866 5_Repair	Q010102	Posts, screws and prefabricated elements as well as auxiliary parts for the restoration of teeth	532866	16-202