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Certification Department

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TÜV Rheinland LGA Products GmbH • 51105 Köln

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

Contact

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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(AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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.

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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

Digital unterschrieben von Karsten Kluge
Datum: 2024.05.16 16:59:50 +02'00'

i.V. Dr. Karsten Kluge
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.	++E2265327725QP	IIa	N/A	HD 60135991 0001 #0197
36.	++E2265327723SJN	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.	++E226532810CDSDR	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.	++E226533078UStLT	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 <u>NOT</u> 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	XXXXXXXXX	Addition of device XYZ to the list
YYYY/MM/DD	XXXXXXXXX	Removal of device XYZ to the list