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Self-declaration – regarding the transition period (Regulation (EU) 2023/607) from MDD to MDR

The Declarations of Conformity of **Gebrüder Martin GmbH & Co. KG**, which are based on Council Directive 93/42/EEC (MDD) will continue to be valid for class I, IIa, IIb and III without modification beyond 26 May 2024 until 31 December 2027/2028.
Simple class I devices have to fulfill already since 26 May 2021 the requirements for Medical Device Regulation (EU) 2017/745 (MDR) – no extended transition period applies.

This self-declaration is justified by law with the Article 120.3c of the Medical Device Regulations (EU) 2017/745 (MDR) as amended by Regulation (EU) 2023/607 of the European Parliament regarding the transitional provisions for certain medical devices. The MDD-Declarations of Conformity for all classifications higher than class I, the following modified transition period applies, depending on the classification:

- 31 December 2027: class III devices and class IIb implantable devices except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors.
- 31 December 2028: class IIb implantable devices that are sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors, class IIb non-implantable devices, class IIa devices, class I sterile/measuring devices (class Is, Im), and devices that did not require notified body involvement under MDD but do so under MDR (e.g. class I reusable surgical instruments (class Ir)).

Regarding the devices specified in this self-declaration, we declare that:

- Those devices continue to comply with Directive 93/42/EEC.
- There are no significant changes in the design and intended purpose.
- The devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health.
- A formal application was lodged with the notified body in accordance with Section 4.3, first subparagraph of Annex VII of the MDR for conformity assessment in respect of these devices on 23.10.2023. Please see the annex for the following information: name and ID of the notified body, EC Certificate number and scope of devices.
- A written agreement has been signed in accordance with Section 4.3, second subparagraph of Annex VII of the MDR. The written agreement was received on 01.11.2023. Please see the annex for the following information: name and ID of the notified body, EC Certificate number and scope of devices.
- In compliance with Article 10(9) of the MDR, a quality management system (QMS) has been put in place.

The medical devices covered by this self-declaration are listed in the following table in the annex. For these articles, the conditions for an extension of the transition period in accordance with Regulation (EU) 2023/607 are fulfilled.

Please see also page two and three *"Factsheet for authorities in non-EU/EEA states on medical devices and in vitro diagnostic medical devices":* MDR-IVDR_FS_third-countries_en (europa.eu). Based on the Medical Device Regulations (EU) 2017/745 (MDR) as well as Regulation (EU) 2023/607, **the MDD-Declarations of Conformity of Gebrüder Martin GmbH & Co. KG still remain valid** until 31 December 2027/2028.
You can find further information at, https://www.klsmartin.com/en/company/legal-merger/. If you have any questions, you can also reach us at info@klsmartin.com.

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Annex

Medical devices covered by this self-declaration and for which the notified body **DQS Medizinprodukte GmbH, NB 0297** is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive listed in the table below.

Applicable certificates:
1. EC Certificate, Full quality assurance system: 210299 MR2, 170776073 (NB 0297)

Scope of medical devices:

Device name and Basic UDI-DI	MDR Device classification	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
8100442 **Maxium** **40576051775Q**	Class IIb	RF-surgery units Medical RF-surgery units for general and special applications Maxium (97, 106, 178)	210299 MR2 170776073 (NB 0297)
8100436 **MD62** **BUDI not assigned**	Class IIb	RF-surgery units Medical RF-surgery units for general and special applications HF-Chirurgiegerät MD62 (106)	210299 MR2 170776073 (NB 0297)
8100511 **TD-00136** **40576051775Q**	Class IIb	Argon Beamer Maxium Beamer (98)	210299 MR2 170776073 (NB 0297)
8100559 **TD-00136** **40576051785S** **40576053485T**	Class Iib	Argon Beamer MAXIUM SMART BEAM (143)	210299 MR2 170776073 (NB 0297)
8100496 **TD-00133** **40576053435H**	Class IIb	RF-surgery units Medical RF-surgery units for general and special applications HF-Chirurgiegerät ME102) (104)	210299 MR2 170776073 (NB 0297)
8100449 **TD-00129** **40576053425F**	Class IIb	RF-surgery units Medical RF-surgery units for general and special applications HF-Chirurgiegerät Minicutter (105)	210299 MR2 170776073 (NB 0297)
8100554 **TD-00153** **40576051785S**	Class IIb	RF-surgery units Medical RF-surgery units for general and special applications	210299 MR2 170776073 (NB 0297)

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8100591 **TD-00153** **40576051785S**		MAXIUM SMART C (142)	
HF-Handgriff steril, single use **TD-00XXX not assigned** **BUDI not assigned**	Class IIb	Handles for RF-surgery Handgriff semidisposable HANDGRIFF, 2 TASTEN, 3 PIN, 2,4MM, 3M, 90 (89, 90,171)	210299 MR2 170776073 (NB 0297)
HF-Handgriff steril, single use **TD-00XXX not assigned** **BUDI not assigned**	Class IIb	Handles for RF-surgery HF- Handgriff steril, inkl. aktive Elektrode und Rauchgas-absaugung, single use + HF- Handgriff steril, inkl. aktive Elektrode, single use, 90 (89, 91,172)	210299 MR2 170776073 (NB 0297)
8100492 **TD-00132** **40576053925W**	Class IIb	Handles for RF-surgery MABS-Handgriff für starre Applikatoren (111, 112)	210299 MR2 170776073 (NB 0297)
8100522 **TD-00139** **405760539462**	Class IIb	Electrodes MABS-Snare-Sonden (disposable) (110)	210299 MR2 170776073 (NB 0297)
8100514 **TD-00138** **40576053935Y**	Class IIb	Electrodes MABS flexible Sonden (disposable) (108)	210299 MR2 170776073 (NB 0297)
8100492 **TD-00132** **40576053925W**	Class IIb	Electrodes MABS-Beam-Elektroden (492)	210299 MR2 170776073 (NB 0297)
8100598 **TD-00168** **405760538867**	Class IIb	Electrodes 86a Wiederverwendbare Neutralelektrode (92, 178)	210299 MR2 170776073 (NB 0297)
8100585 **TD-00160** **40576053505E**	Class IIb	Electrodes Einmalneutralelectrode (96, 177)	210299 MR2 170776073 (NB 0297)
8100593 **TD-00167** **40576053495V**	Class IIb	Electrodes Aktiv Elektroden (93, 94, 95, 175)	210299 MR2 170776073 (NB 0297)
8100598 **TD-00168** **405760538867**	Class IIb	Electrodes Wiederverwendbaren Neutralelektroden (178)	210299 MR2 170776073 (NB 0297)
8100507	Class IIb	Clamps, forceps	210299 MR2

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TD00134 **405760538765**		MarClamp Bipolare Klemmen für die Gefäßversiegelung (114)	170776073 (NB 0297)
8100530 **TD-00144** **40576053395S**	Class IIb	Clamps, forceps MarSeal 10mm gebogenes Maulteil (115)	210299 MR2 170776073 (NB 0297)
8100529 **TD-00143** **40576053465P**	Class IIb	Clamps, forceps Bipolare Pinzetten - Non-Stick red (120)	210299 MR2 170776073 (NB 0297)
8100529 **TD-00143** **40576053465P**	Class IIb	Clamps, forceps Non Stick flush, bipolare Spülpinzetten (138)	210299 MR2 170776073 (NB 0297)
8100530 **TD-00144** **40576053395S**	Class IIb	Clamps, forceps MarSeal slim (144)	210299 MR2 170776073 (NB 0297)
8100513 **TD-00137** **405760539564**	Class IIb	Clamps, forceps MarLap - Bipolare Instrumente für die Laparoskopie (121)	210299 MR2 170776073 (NB 0297)
8100597 **TD-00143** **405760538969**	Class IIb	Clamps, forceps Monopolare Pinzetten (118)	210299 MR2 170776073 (NB 0297)
8100597 **TD-00143** **405760538969**	Class IIb	Clamps, forceps Bipolare Pinzetten (120)	210299 MR2 170776073 (NB 0297)
8100524 **TD-00141 (Class I)** **40576051805D**	Class IIa	products for smoke evacuation MARVAC SMOKE EVACUATION SYSTEM (134)	210299 MR2 170776073 (NB 0297)
8100560 **TD-00141** **40576051795U**	Class IIa	products for smoke evacuation maxium smart VAC (139)	210299 MR2 170776073 (NB 0297)
20-827-02 **TD-00120** **405760530457**	Class III	UHP (prosthesis for wrist joint) Ulna Kopf Prothese (72, 189)	210299 MR2 170776073 (NB 0297)
20-826-02 **TD-00119** **40576052945V**	Class III	Finger joint Capflex PIP (73, 190)	210299 MR2 170776073 (NB 0297)

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14-006-06 **TD-00058** **405760550NF**	Class IIb excluding Class IIb implantable non-WET	CranioXpand (156)	210299 MR2 170776073 (NB 0297)
21-833-02 **TD-00082** **40576051855P**	Class IIa	Sterile scalpels / blades Sterile Skalpelle und Skalpellklingen (88, 166, 188)	210299 MR2 170776073 (NB 0297)
18-840-01 **TD-00051** **40576051365A**	Class IIb	Drill bits OMF surgery Schraubendreher-Klingen(159)	210299 MR2 170776073 (NB 0297)
19-809-02 **TD-00079** **40576051455B (sterile)** **40576051465D**	Class IIa	Repositioning Instruments Repositionsinstrumente (162)	210299 MR2 170776073 (NB 0297)
18-840-01 **TD-00051** **40576051365A**	Class IIa	Screwdriver blades Schraubendreher-Klingen (159)	210299 MR2 170776073 (NB 0297)
19-800-01 **TD-00044** **40576051385E** **40576051395G**	Class IIa	Bending Templates Biegeschablonen, unsteril (27, 164)	210299 MR2 170776073 (NB 0297)
19-800-01 **TD-00044** **40576051375C**	Class IIa	Bending Templates Biegeschablonen, steril (165)	210299 MR2 170776073 (NB 0297)
18-839-01 **TD-00029** **405760513456**	Class IIa	Rotating cutting devices rotierende Schneidwerkzeuge, unsteril (160)	210299 MR2 170776073 (NB 0297)
21-846-01 **TD-00111** **40576053285M**	Class I devices that qualify as re-usable surgical instruments	Rotating cutting devices rotierende Schneidwerkzeuge, unsteril (160)	210299 MR2 170776073 (NB 0297)
18-839-01 **TD-00029** **405760513354**	Class IIa	Rotating cutting devices rotierende Schneidwerkzeuge, steril (161)	210299 MR2 170776073 (NB 0297)

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18-839-01 **TD-00029** **405760513354**	Class IIa	Rotating cutting devices IXOS Spiralbohrer (49)	210299 MR2 170776073 (NB 0297)
18-839-01 **TD-00029** **405760513354**	Class IIa	Rotating cutting devices Recos Spiralbohrer (54)	210299 MR2 170776073 (NB 0297)
18-839-01 **TD-00029** **405760513354**	Class IIa	Rotating cutting devices HBS 2 Spiralbohrer (60)	210299 MR2 170776073 (NB 0297)
18-839-01 **TD-00029** **405760513354**	Class IIa	Rotating cutting devices Knochenbohrer (187)	210299 MR2 170776073 (NB 0297)
22-801-02 **TD-00XXX (not assigned)** **VK M6** **BUDI (not assigned)**	Class IIb	Service Head Versorgungskonsole (3)	210299 MR2 170776073 (NB 0297)
97-008-03 **TD-00055** **40576051635D**	Class IIa	Angled screwdriver Winkelschraubendreher (197)	210299 MR2 170776073 (NB 0297)
37-000-02 **TD-00083** **40576051625B**	Class IIa	Suction Units, Suction Cannulae, Irrigation Cannulae Saugkanülen (38, 155)	210299 MR2 170776073 (NB 0297)
37-000-02 **TD-00083** **40576051625B**	Class IIa	Suction Units, Suction Cannulae, Irrigation Cannulae Insuflationskanülen (41)	210299 MR2 170776073 (NB 0297)
21-856-02 **TD-00112** **40576053335E**	Class IIa	marTract marTract Retractor System (140)	210299 MR2 170776073 (NB 0297)
17-000-02 **TD-00081** **405760565NU**	Class IIa	Wound spreading systems Wundspreizer (40)	210299 MR2 170776073 (NB 0297)

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17-000-02 **TD-00081** **405760565NU**	Class IIa	Wound spreading systems Rippensperrer (39)	210299 MR2 170776073 (NB 0297)
24-000-11 **TD-00077** **405760516159**	Class I devices with a measuring function	N/A	N/A – Device did not require a Notified Body certificate under Directives
21-835-01 **TD-00114** **40576053535L**	Class I devices with a measuring function	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00002 **19-805-02** **405760514153**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00012 **14-006-05** **405760553NM**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00016 **19-806-01** **405760514255**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00018 **15-007-01** **405760559NZ**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00052 **19-804-01** **40576051404Z**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00067 **16-000-01** **405760560NJ**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives

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Persönlich haftende Gesellschafterin

KLS Martin Verwaltungs SE
KLS Martin Platz 1
78532 Tuttlingen · Germany

Sitz der Gesellschaft: Tuttlingen
Registergericht: Stuttgart
Handelsregister: HRB 791599

Geschäftsführende Direktoren:
Christian Leibinger, Michael Martin, Thomas Hipp

Verwaltungsrat:
Christian Leibinger (Vorsitzender), Karl Leibinger

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Device name and Basic UDI-DI	MDR Device classification	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
TD-00068 17-000-01 405760563NQ	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00069 05-000-01 405760537NP	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00070 14-000-01 405760549NW	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00071 18-000-01 405760566NW	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00072 03-000-01 405760535NK	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00073 06-000-01 405760538NR	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00074 08-000-01 405760539NT	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00076 20-000-01 40576051485H	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00093 21-830-01 40576053986A	Class I devices that qualify as re-usable surgical	N/A	N/A – Device did not require a Notified Body certificate under Directives

KLS Martin SE & Co. KG

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Deutsche Bank:
IBAN DE25 6537 0075 0218 4000 00
BIC DEUTDESS653

Commerzbank AG:
IBAN DE88 6944 0007 0241 2153 00
BIC COBADEFF694

Kommanditgesellschaft

KLS Martin SE & Co. KG
KLS Martin Platz 1
78532 Tuttlingen · Germany

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Handelsregister: HRA 450196
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Device name and Basic UDI-DI	MDR Device classification	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
	instruments		
TD-00096 **21-843-01** **40576053255F**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00101 **21-845-01** **40576053275K**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00111 **21-846-01** **40576053285M**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00115 **21-836-01** **40576053195L**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives

Tuttlingen

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Ursula Rösler
Name des Unterzeichners: Ursula Rösler
Signiergrund: Ich genehmige dieses Dokument
Signierzeit: 2024-05-16 | 5:14 PM MESZ
23146E9441084B3CBC60F91DAE5DD035

i.V. Ursula Rösler
Senior Director Regulatory Affairs (PRRC)
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A company of the KSL Martin Group

DocuSigned by:
Anton Mittermüller
Name des Unterzeichners: Anton Mittermüller
Signiergrund: Ich genehmige dieses Dokument
Signierzeit: 2024-05-16 | 5:18 PM MESZ
C6A9E97A5E864548B077EAC260CF9AEA

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