

TÜV Rheinland LGA Products GmbH • 51105 Köln

KABE-Labortechnik GmbH
Jägerhofstrasse 17
51588 Nümbrecht
Germany

Contact

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

Date July 12, 2024

Notified Body Confirmation Letter

Reference. : KABEL_PLA0HZ_2024-06-18, order #1160753

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:

KABE-Labortechnik GmbH
Jägerhofstrasse 17
51588 Nümbrecht
Germany
SRN Number (if available): DE-MF-000011861

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

Board of Management

Dipl.-Ing.
Thomas Weigand, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Nuremberg HRB 26013
VAT No.: DE 811835490

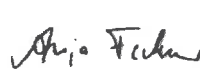
Chairman of the
Supervisory Board

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

 Anja Fechner
2024.07.12 11:14:22
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Dipl.-Ing.
Anja Fechner
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
BF 21 G grün 200 mm security	Ila	N/A	HD 60150763 0001 NB 0197
BF 22 G schwarz 200 mm security	Ila	N/A	HD 60150763 0001 NB 0197
AM G 46 21G grün 100 mm security	Ila	AM G 46 BF grün 100 mm security	HD 60150763 0001 NB 0197
AM G 46 22G schwarz 100 mm security	Ila	AM G 46 BF schwarz 100 mm security	HD 60150763 0001 NB 0197
AM G 46 21G grün 178 mm security	Ila	AM G 46 BF grün 178 mm security	HD 60150763 0001 NB 0197
AM G 46 22G schwarz 178 mm security	Ila	AM G 46 BF schwarz 178 mm security	HD 60150763 0001 NB 0197
Sangocan® 21G grün 100 mm security	Ila	Sangocan V 21 G grün 100 mm security	HD 60150763 0001 NB 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
Sangocan® 22G schwarz 100 mm security	Ila	Sangocan V 22 G schwarz 100 mm security	HD 60150763 0001 NB 0197
Sangocan® 21G grün 178 mm security	Ila	Sangocan V 21 G grün 178 mm security	HD 60150763 0001 NB 0197
Sangocan® 22G schwarz 178 mm security	Ila	Sangocan V 22 G schwarz 178 mm security	HD 60150763 0001 NB 0197
Kombi-Sangocan® 21G grün 100 mm security	Ila	Kombi-Sangocan V 21 G grün 100 mm sec.	HD 60150763 0001 NB 0197
Kombi-Sangocan® 21G grün 178 mm security	Ila	Kombi-Sangocan V 21 G grün 178 mm sec.	HD 60150763 0001 NB 0197
Kombi-Sangocan® 22G schwarz 178 mm security	Ila	Kombi-Sangocan V 22 G schwarz 178 mm sec.	HD 60150763 0001 NB 0197
Sangocan V 20 G gelb 100 mm security	Ila	N/A	HD 60150763 0001 NB 0197
AM G 46 20G gelb security	Ila	AM G 46 K gelb security	HD 60150763 0001 NB 0197
AM G 46 21G grün security	Ila	AM G 46 K grün security	HD 60150763 0001 NB 0197
AM G 46 22G schwarz security	Ila	AM G 46 K schwarz security	HD 60150763 0001 NB 0197
Sangocan® 20G gelb security	Ila	Sangocan 20 G gelb security	HD 60150763 0001 NB 0197
Sangocan® 21G grün security	Ila	Sangocan 21 G grün security	HD 60150763 0001 NB 0197
Sangocan® 22G schwarz security	Ila	Sangocan 22 G schwarz security	HD 60150763 0001 NB 0197
Kombi-Sangocan® 20G gelb security	Ila	Kombi-Sangocan 20 G gelb security	HD 60150763 0001 NB 0197
Kombi-Sangocan® 21G grün security	Ila	Kombi-Sangocan 21 G grün security	HD 60150763 0001 NB 0197
Kombi-Sangocan® 22G schwarz security	Ila	Kombi-Sangocan 22 G schwarz security	HD 60150763 0001 NB 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
AM G 46 20G gelb	Ila	AM G 46 K gelb	HD 60150763 0001 NB 0197
AM G 46 21G grün	Ila	AM G 46 K grün	HD 60150763 0001 NB 0197
AM G 46 22G schwarz	Ila	AM G 46 K schwarz	HD 60150763 0001 NB 0197
Sangocan® 20G gelb	Ila	Sangocan 20 G gelb	HD 60150763 0001 NB 0197
Sangocan® 21G grün	Ila	Sangocan 21 G grün	HD 60150763 0001 NB 0197
Sangocan® 22G schwarz	Ila	Sangocan 22 G schwarz	HD 60150763 0001 NB 0197
Kombi-Sangocan® 20G gelb	Ila	Kombi-Sangocan 20 G gelb	HD 60150763 0001 NB 0197
Kombi-Sangocan® 21G grün	Ila	Kombi-Sangocan 21 G grün	HD 60150763 0001 NB 0197
Kombi-Sangocan® 21G grün (PT)	Ila	Kombi-Sangocan 21 G grün (0,8 x 25 mm)	HD 60150763 0001 NB 0197
Kombi-Sangocan® 22G schwarz	Ila	Kombi-Sangocan 22 G schwarz	HD 60150763 0001 NB 0197
KABE MBU-Kapillaren 115 µl A-Ø 2,1 mm I-Ø 1,3 mm zu 5 St. verpackt, steril	Is	MBU-Kapillaren 115 µl, AD= 2,1 mm, ID= 1,3 mm, zu 5 Stück verpackt, steril	HD 60150763 0001 NB 0197
KABE MBU-Kapillaren Na 115 mit Kapillarhalter SR 200 steril	Is	NA 115 mit Kapillarhalter SR 200, steril	HD 60150763 0001 NB 0197
KABE MBU-Kapillaren BK 100 dünner Ø balanciertes Heparin mit SR 200 steril	Is	BK 100 dünner Ø neutr. Hep., mit SR 200, steril	HD 60150763 0001 NB 0197
KABE MBU-Kapillaren BK 85 Ø 1,9 x 85 mm balanciertes Heparin *SD* mit SR 200 steril	Is	BK 85 Ø 1,9 x 85 mm neutr. Hep. *SD* mit SR 200, steril	HD 60150763 0001 NB 0197
KABE MBU-Kapillaren BK 110 Ø 1,9 x 110mm balanciertes Heparin *SD* mit SR 200 steril	Is	BK 110 Ø 1,9x110mm neutr. Hep. *SD* mit SR 200, steril	HD 60150763 0001 NB 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
KABE MBU-Kapillaren NH 150 mit Kapillarhalter SR 200 steril	Is	NH 150 mit Kapillarhalter SR 200 steril	HD 60150763 0001 NB 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
2024/07/12	KABEL_CL607_2024-07-12	Initial issue