TÜVNORD

TÜV NORD CERT GmbH, Am TÜV 1, 45307 Essen, Germany

Wagner Klinikbedarf e.K. Inh. Ingo Wagner
Ronsdorfer Str. 188 - 190
42855 Remscheid

TÜV NORD CERT GmbH
Am TÜV 1
45307 Essen
Germany

Phone: +49 201 825 2236

medical@tuev-nord.de
tuev-nord-cert.com/en

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Reference	Contact	Direct Dial	Date
No.: 44235200155 Order 8003067385	E-Mail: medical@tuev-nord.de	Tel.: +49 201 825 2236	30 January 2024

Notified Body Confirmation Letter
Reference: EC-Certificate acc. 93/42/EEC Annex V, No.: 44 235 200155
Order 8003067385

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 NORD CERT GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0044 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:

Wagner Klinikbedarf e.K. Inh. Ingo Wagner
Ronsdorfer Str. 188 - 190
42855 Remscheid
Germany
SRN Number: DE-PR-000005010

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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

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:

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

TÜVNORD i. V.
Digital unterschrieben von Mühlenberg Kevin
Datum: 2024.01.30 14:02:15 +01'00'

i. V. Kevin Mühlenberg
Head of Project Management
Medical Devices International
TÜV NORD CERT GmbH
Notified Body for Medical Devices

TÜVNORD i. A.
Digital unterschrieben von Mestmacher Bodo
Datum: 2024.01.30 13:53:32 +01'00'

i. A. Bodo Mestmacher
TIC Management
Medical Devices International
TÜV NORD CERT GmbH
Notified Body for Medical Devices

TÜVNORD

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
2 x Schlitztuch 260 x 220 cm, **Aan/afsluitpakket voor Catheter** **Aansluitpakket voor Shunt** **Abdeck-Set Nr. 1** **Abdeck-Set Nr. 3** **Abdeck-Set Nr. 5** **Abdecktuch 180 x 180 cm** **Abdecktuch 180 x 180 cm, Klebestreifen 5 x 180 cm** **Abdecktuch 220 cm x 300 cm, sk** **Abdecktuch 220 x 300 cm** **Abdecktuch 269 x 157 cm** **Abdecktuch seitlich 91 x 112 cm, sk** **Abdominal Set** **Abszessinzisions-Set** **Abwasch-Set** **ACH Universal** **ACVB-Set** **AKE-Set** **Akne Inversa + Proktoskopie** **all in one Intravitreales Basis-Injektions-Set** **Anaal-Tray** **Anästhesie-Basis-Set** **Anästhesie-Set** **Anästhesietupfer Pack** **Angio Set** **Angiographie-Set** **ANGIO-Set** **Anwendungs-Set** **Application-Set** **Armlehnenbezüge mit Tape** **Arteriapaineenmittaussetti** **Arthro-Set** **Arthroskopie Knie 2** **Arthroskopie Set** **Arthroskopie-Set Sulingen** **ASK Set** **ASK-Knie** **Augenabdecktuch 134 x 108 cm** **Augenabdecktuch 80 x 92 cm** **Augenabdecktuchsystem** **Augenklappe transparent, 9-er Bohrung,** **Augen-OP-Set** **Augen-Set** **Augentuch 135 x 140 cm** **Augentuchsystem 134 x 108 cm** **Augentuchsystem 75 x 75 cm** **Basis Set** **Basis Set ASK KNIE** **Basis Set ASK Schulter/OSG/EBG** **Basis Set EKH** **Basis Set HPM** **Basis Set Hüft-TEP** **Basis Set Neuro**	N/A	N/A	EC-Certificate acc. 93/42/EEC V Certificate No.: 44 235 200155, TÜV NORD CERT GmbH

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
Basis Set POK Basis Set Spongiosaplastik hinterer BK Basis Set U-6 Basis Set UWC Standard Basis-Kokon-Set II Basis-Set Basis-Set groß Basis-Set klein Basis-Spinalanästhesie-Set Basistray Bauch-Set groß Bauch-Set klein Becher, 250 ml Beistelltisch-Kokon-Set III BETA-Klemme, 24 cm, blau Bevallingsetje Biopsie pakket Biopsie-Set Mamma Blaascatheterset Blasenkatheter-Set Blasenkatheter-Set - OHNE Schlitztuch Blasenkatheter-Set mit Schlitztuch Breuk-Tray Catheterset CAVA-Set CM Peittelypakkaus Keskuslaskimokatetr Colposcopie-Set Coronar Set CT Punktions-Sets CT-Abdeckung CT-Punktions-Set CVK-Pakkaus CVK-Setti Cystoskopie-Set Da Vinci Dauerkatheter-Set Debridement-Set Dental-Set Depperset Desinfektions-Set Desinfektions-Set Geburt Desinfektions-Set Tagesklinik Gyné DK-Set Drahtschale 2500ml Drainage-Set ECLS-Instrumenten / Klemmen-Set ECLS-Set ECMO/ECLS Set END OP-Tisch-Set Endokrinologie-Set Endoskopische Eingriffe Endovaskular-Set EPU Set 2 ERCP Set ERCP-Abdecktuch ERCP-Standard-Set Ergänzungs-Set Mamma Erwachsenen Herz Set			

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
E-Tuch-Abdeckung Eventrecorder Set Extension OS-Set Extremitäten-Set Fadenentfernungs-Set Fixierbinde 6cm Fundoplikatio-Set Fuß-Set gatlaken 90 x 75 cm met venster dia 10 cm Geburten-Set Gefäß Set Gefäßchirurgie Basisset Leiste GHZ EVAR Tray GHZ Heup Tray GHZ Knietray GHZ Start Tray Großes Extremitäten-Set Großes Laparotomie Set U 7 Grund Set ORTHO GYN Rektale Abdeckung Gyn-Uro-Set Halb-Transparentes Lochtuch 120 x 150 cm Hand Plastisch POK Hand Set Handpakket Handset Hand-Set Herz Set, Herzkatheter Set Herz-Set HLM-Abdeckset HNO-Set HSK-Set Hüft Endoprothetik Hüft Set Anterior Hüft Set UCH Hüft TEP Set Hüft-/ Schulter-Verband-Set Hüft/Knie-Set Hüft-Infiltrations-Set Hüft-Set Hüft-Set Seitenlage Hüft-Tep Hüft-Tuch Eckernförde HWS Set Hysteroskopie-Cystoskopie-Set Implantations - ECLS Implantations-Set Individual-Set Infiltrations-Set Inhoud set Injections-Set Instillations-Set Instrumententischbezug 95 x 195 cm Instrumententisch-Kokon-Set II / XL Instrumententisch-Kokon-Set V / S			

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
Intravitreales Injektions-Set Inzisionsfolie 10 x 20 cm, mit Fingerlift IVI-Set IVI-Set Nr. 10058 IVI-Tray IVOM-Set IVOM-Set TYP 101 IVOM-Set TYP 102 IVOM-Set TYP 103 IVOM-Set TYP 104 IVOM-Set TYP 111 IVT Maria ZH P4 MZNL Kaakset Rivas Kanylointisetti Katarakt-Set Katarakt-Set Nr. 4b Katarakt-Set Nr. 4c Katarakt-Set Nr. 5 Katarakt-Set Nr. 6 Katheterisatieset Katheter-Legeset Katheterset Katheter-Set Katheter-Set II ohne HS Katheter-Set Nr. 59 Katheter-Set WaWuMed I Kinder Herz Set Kinderherz Set Kinderset klein Klappentuch 75 x 75 cm Kleines Eingriff-Set Kleines OP Set Kleines-Set Klina Oogset Knie Arthroskopie KNIE ASK KR Knie Endoprothetik Knie TEP Set Knie-Arthroskopie Knie-ASK-Set Knie-Prothesen-Set Knie-Set Knie-TEP Knie-Tep Kokon-Zusatzset Viscosevlies VI Kompressen-Set Kopf Set, Kopfset, Krankenunterlage 60x60cm Kreißsaal-Set KrinKo Abdeckung Beistelltisch Kunststoffschale, 7.000 ml LAKEN met kleefstrook 100 x 90 cm LAKEN met kleefstrook 300 x 183 cm Laparoskopiapakkaus Laparoskopie Set U 7 Laparoskopie-Set Laparotomie Set			

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
Lap-Pelvi-Set Laser-Set Lasiaisinjektio 1 ster LAVH / LASH / LATH Lege-Set Lid/Facelift/Nase/Ohr-Set Lid-Set Lijnenset L-Set LSK-Set L-Tuch Lumbalpunktions-Set LWS Set Mamma-Set MAP-Set Master Dialysis Pack MBB-Set MIC-Galle Set MIC-Hernien Set MIC-Kinderset MIC-Set MRSA-Set Strikte Isolatie Oranje M-Set Muller Tray Naht-Set Neuro Set Neuro Wirbelsäule Neustray Notfall & Gefäßset Nucleus-Set Oberarm/Oberschenkel/Wirbelsäule Onderlaken 173 cm x 180 cm zk OP Set OP-Basis-Herz-Set OP-Set Ortho Set Oxford Set Pacco Angiografia Pack de désinfection ophtalmique Pack voie bass 1 partusset VK PDK-Set Pelviskopie-Abdeckung Peridual-Spinal-Set Perineal-CV-Tuch 187 x 241 cm Perineales Klebepad PICC Set PICC SET Pijnkliniek-Set Plastikschale, 2.500 ml, blau Plastisch Algemeen, Plastisch Ambulant Pneumo-Set Poets-Set 1 Poets-Set 2 Port-Set Porttuch 220 x 330 cm Procto			

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Punktions-Set Punktions-Set Muri Punktions-Set Notfall Rautentuch Rectum Set Regional-Anästhesie-Basis-Set Regional-Anästhesie-Set RMH Thoraxset Röntgen Set Röntgenset Sanaset Desinfektion Säuglings-Set Schädel-Set Schale für Drähte Schamtuch 20 x 60 cm Schaumstoff-Nadelsammler 6 x 6 x 3,5 cm Schlitztuch 193 x 304 cm, Schlitz 10 cm Schlitztuch Set Schrittmacherset Schulter ASK-Set Schulter Set Schulter-Arthroskopie Schulterarthroskopie Set Schulterprothesenset Schulter-Set Schulter-TEP-Set Schutzpolsterhülle, KLEIN Schutzpolsterhülle, MITTEL Sectio - SET Sectio Set Seitentuch 90 x 130 cm Sekretbeutel-Universal Set artrografia Set chir main Set Cordon Set d'anesthésie Set disinfezione radiology open Set für kleine Eingriffe Set Große Eingriffe Set Infiltration Set petite chirurgie Set Port-à-Cath-Punktion Set posa drenaggio toracico Set teli anestesia Set universale radiologia EOC Sigmaresektion-Set SMMS-OP-Kittel Gr. L, blau, SMMS-OP-Kittel Gr. XL, blau Spinal-Anästhesie-Set Spinal-Set Spoel-Set, blaas, Nr. 3 Spritzen-Set, Steinschnitt Set Sterilüberzug Strabimus Tray Strabismustray Struma-Set Subclavia-Set IPS			

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Sutuur setje TA-Set TAVI Abdecksystem Teil-Angio-Set TEP-Set TFESI-Set Thorax-Drainage-Set Thorax-Set Transparenter Ablaufbeutel mit Clip Transparentes Abdecktuch Transport-Kokon-Set IV Transport-Kokon-Set VII, Sondergröße XL Trauma-Set Tray Katarakt-Set Trimano-Application-Set Trousse accouchement Trousse cervicale Trousse césarienne Trousse Grande Tomie Trousse Hernie Discale Trousse Stomato Trousse Uro-résection Tupferset mit Schale TUR-Set TUR-Set Uroviva U/O Hüfte U/O Knie U-Bar-Set Trauma Ultraschallbezug Argos 15 x 150 cm Uni Set Uni Set Large Unità di trattamento punzione midollo e biopsia Universal Set Universal-Set Anästhesie Universal-Set klein Universal-Set Plus Untere Extremitäten-Set Unterlage, wasserfest 60 x 60 cm Urin-Set U-Tuch Set U-Tuch wie U-Bar VII U-Tuch-Set Varizen-Set Varizenset Verband-Set Augen Verbandwechsel-Set Verbandwechsel-Set Spülung klein Verbandwisselset Vertikal-Set Vertikaltuch Vertikaltuch HNO Vertikaltuch Set Viscosevlies 120 x 150 cm, blau Viscosevlies 150 x 200 cm Vorbereitungsset Portkatheter Wasch Set Klein Wattenbollen-Set á 5 Stück 2 gr.			

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Wattenbollen-Set Nr. 2 **Watte-Set** **Wirbelsäulen Set** **WS Set** **Wund-Set** **Wundversorgungs-Set** **XL-Kokon-Set I** **zelfklevend instrumentenzak 1 compartiment 35 x 40 cm** **ZVK Anlage Set** **ZVK-Lege-Set** **ZVK-Set Safety** **Zysto Set** **Zysto Set RUIT**			

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
2024/01/30	Rev.0	Initial issue / P111F007(e)_Rev.0_2023-11-30