

Confirmation Letter Template Regarding Amending Regulation (EU) 2023/607



P.J. Dahlhausen & Co. GmbH
Adam-Riese-Strasse 4
D-50996 Köln /Germany

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
15692	713335765	+49 40 840521-142		2024-06-19	1 of 6
Nassim.Bilginer@tuvsud.com					

TÜV SÜD Product Service GmbH Receipt of formal application

Reference: 713335765

To whom it may concern,

Confirmation of the status of a formal application in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received **a formal application** in accordance with Section 4.3, first subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: DE-MF-000006357

The devices covered by the formal application mentioned above are identified in the Table below.

Please note that this letter only confirms the status of the formal application.

To benefit from the additional transitional provisions in the framework of Regulation EU 2023/607, TÜV SÜD Product Service GmbH and the manufacturer need to sign a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR latest until 26 September 2024.

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-06-28

TÜV SÜD Product Service GmbH
Medical and Health Services

A handwritten signature in blue ink, appearing to read 'G. Ullrich', written over a horizontal line.

SIGN-ID 932832

Gunnar Ullrich

Expertise Manager

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Devices covered by the formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR

Device name or Basic UDI-DI (under MDR application)	
Risk Class IIb	
Device name:	Basic UDI-DI:
Neutralelektroden / Neutral electrodes	34342Neutralelektrode3D
Silikon-Ballon-Katheter / Silicone-Balloon-Catheter	34342SillikonballonND
Risk Class IIa	
Device name:	Basic UDI-DI:
- Absaugkatheter / Suction Catheter - Tracheostoma Katheter / Suction catheter for tracheostoma	34342AbsaugkatheterWU
Hautklammergerät / Skin stapler	34342HautklammergeraetCK
- Aerosol Sauerstoffmaske / Aerosol mask - Beatmungsmaske / Respiration mask - Gesichtsmaske m O2-Anschluss / Face tent - Sauerstoffmaske / Oxygen mask - Sauerstoffmaske, Venturi / Air entrainment mask "Venturi" - Taschenmaske / Pocket Mask - Tracheostomiamaske / Tracheostomy mask	34342SMaskeZQ
Applikationskatheter / Application catheter	34342KatheterapliHT
Spülschlauch/Irrigation Tube	34342SpuelsFA
Bakterien-/Virenfilter / Bacterial-/Viral-Filter	34342Filter79
- Beatmungsbeutel / Resuscitator - Beatmungsbeutel-Set / Resuscitator set	34342BeatmungsbGF
- Beatmungsschlauch / Smoothbore tubing - Beatmungssystem / Breathing circuit - Gänsegurgel / Catherer mount - InEx- Beatmungsschlauch / Closed Coaxial Respiration system	34342BeatmungsbH9
Biopsie Hautstanze / Dermal Biopsy punch	34342HautstanzeY3
Darmrohr / Rectal tube	34342DarmrohrXL
Orthopädischer Sauger / Suction cannula orthoped.	34342OrthosaugerMG
Drainage / Drain	34342DrainageUD
- Drainage Easy Flo / Easy-flo Drainage - Passiv-Drainage / Passive-Drainage - Redon-Drainage / Redon drain	34342RDrainage7M

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Device name or Basic UDI-DI (under MDR application)	
Duodenalsonde / Duodenal tube	34342SondeD9Y
Embolektomiekatheter / Embolectomy catheters	34342EmbolekkVQ
- Endotrachealtubus Magill / Endotracheal Magill tubes - Endotrachealtubus Magill vorgeformt / Endotracheal Magill tubes Preformed - Endotrachealtubus nasal / Endotracheal tubes nasal - Endotrachealtubus Woodbridge / Endotracheal tubes Woodbridge	34342Endotrachealtubus34
- Frauenkatheter / Vaginal Catheter - Nelatonkatheter / Catheter Nelaton - Tiemannkatheter / Bladder Catheter	34342UrokatheterKD
Gasinsufflationssystem / Insufflation Set	34342GasinsufflationWF
Gasprobenschlauch / Gas Sampling Line	34342GasprobensQA
Gefäßschlinge / Vessel loops	34342GefaessRD
Künstliche Nase / Artificial nose	34342KuenstlicheNase9P
Laryngealmaske / Laryngeal Mask Airway	34342LaryngealmaskeEP
Magensonde / Stomach tube	34342SondeMAJ
Saugset / Suction set	34342SaugAE
Saugansatz / Suction cannula	
Geschlossenes Absaugsystem; OptiFlo / Closed suction system; OptiFlo	34342AbsaugsystemG5
Peep Ventil / PEEP valve	34342PEEPVentilYB
Redon Vakuum-Wunddrainagesystem / Redon Vacuum Wound drainage system	34342Redon6P
- Sauerstoffbrille / Oxygen cannula - Sauerstoffkatheter / Oxygen catheter	34342SauerstoffkF7
Sauerstoffverbindungsschlauch / Sure flow tubing	34342Sauerstoffver3G
Saugansatz Typ Frazier / Suction tip type Frazier	34342FarzierHY
Trachealsaugset / Tracheal-Suction set	34342TrachealsQ8
- Sicherheitsskalpell / Safety scalpel - Skalpelle / Scalpels	34342SkalpelleSL
Silikon Maske / Silicone Mask	34342SilikonMaskeMY
Latex Ballon-Katheter (silikonisiert) / Latex-Balloon-Catheter (silikonised)	34342LatexballonkHE
Skalpellklinge / Surgical blade	34342SkalpellklingeMZ

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Device name or Basic UDI-DI (under MDR application)	
Stuhldrainagesystem / Closed Faecal management system	34342Stuhldrainage73
• Thoraxkatheter / Thoracic catheter • Trokarkatheter / Trocar catheter	34342TKatheterD7
• Vernebler Set / Nebulizer set • Verneblertopf / Nebulizer chamber	34342VerneblerSXF
Wendl Tubus / Nasopharyngeale tube	34342Wendltubus42

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Device name or Basic UDI-DI (under MDR application)	
Risk Class Is	
Device name:	Basic UDI-DI:
- Absaugverbindungsschlauch / Suction connecting tube - Endotrachealer Absaugschlauch / Endotracheal suction tube	34342ASchlauchSQV
Bezug für OP Lampengriff / Cover for surgical light	34342BezugLampeEZ
Copolymer-Untersuchungshandschuhe / Copolymer Examination Gloves	34342CSchuheSG3
Fadentrennmesser / Stich Cutter	34342FadenMS4V
Fadenzieh-Set / Set for Suture Removal	34342FadenziehSA3
Guedeltube / Guedel Airway	34342GuedeltubeN4
Hautklammerentferner / Skin stapler Remover	34342KlammerentPZ
HF-Elektrodenreiniger / Tip Cleaner	34342ElektrodenreinigerLF
- Irrigationssystem / Irrigation system - Irrigationssystembeutel / Bag for irrigation system	34342IrrigationsSTB
Katheter-Set / Catheter sets	34342SetK9H
Mundpflegeset / Oral care kit	34342SetM9M
Nabelklemmen / Umbilical cord clamp	34342Nabelk3F
Reservoir / Reservoir	34342Reservoir2J
Schlauchset / Suction tube set	34342SetS9Z
Schutzhülle für Ultraschallsonde / Protective cover for ultrasound probe	34342SUItraschallK7
Sekret-Beutel / Secretion Bag	34342SBeutel92
Thorax-Drainage Sekretbeutel / Thoracic Drainage Secretion Bag	34342TSBeutelGV
Thoraxdrainagesystem / Thorax Drainage System	34342TSystemNY
Urinbeutel / Urine Bag	34342UBeutelA4
Verschlusskappe / Combi Cap	34342KVerschlussPF
Verschlussstopfen / Plug	34342SVerschlussX7
Videokamerabezug / Video Camera Drape	34342VBezugSAT
Führungstäbe für Endotrachealtubus / Guide rod for Endotracheal tubes	34342Endotrachfuehrung89
Infusionsregler / Infusion Flow Regulator	34342InfusionsWX

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Device name or Basic UDI-DI (under MDR application)	
Infusionssystem / Infusion system	
Risk Class Im	
Device name:	Basic UDI-DI:
Einnahmegläschen / Medicine cup	34342Einnahmeglas7T
Risk Class Im+s	
Device name:	Basic UDI-DI:
Urindrainagesystem D8 mit Messfunktion / Urine drainage system D8 with measuring function	34342UBeuteIMNL