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TÜV®

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Date
17 May 2024

Confirmation of continued appropriate surveillance

To whom it may concern,

On 09.04.2015 the company Promedical AG has entered a contractual relationship (6003104980) with TÜV NORD CERT concerning Conformity Assessment according to directive 93/42/EEC (MDD) (Certificate No.:44 235 150440, validity: 2024-05-26.

With the amendment of regulation (EU) 2017/745 (MDR) by regulation (EU) 607/2023, the validity of MDD certificates was prolonged by law under certain conditions, which are met by Promedical AG:

- On 2024-04-15 Promedical AG has lodged an MDR application (Contract No. 6003160261) for sterile procedure packs which is currently under review by the Notified Body of TÜV NORD CERT.
- Further, no significant changes nor quality defects to products have been obtained so far by TÜV NORD CERT in its annual surveillance audits under EN ISO 13485, Art 120 MDR and assessments. Additionally, Promedical AG also confirms, that no devices are placed on the EU market.

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Audits / Assessments were conducted under the following scopes:

Certificate	Certificate No.	Scope	Validity
EN ISO 13485:2016 +AC:2018+A11:2011	44 221 150440	Production and distribution of sterile and non-sterile medical devices for patient care, wound care and the operating room. Sterilization of healthcare products with ethylene oxide according to DIN EN ISO 11135:2020 and production and sterilization of procedure packs.	2025-09-28
93/42/EEC Annex V	44 235 150440	Disposable medical devices for hospitals	2024-05-26

However, sterile procedure packs are not assigned to any class because they are not "devices" as per EU 2023/745 Art. 2. Further, sterile procedure packs are not subject to a conformity assessment procedure in accordance with Art. 52, but to a procedure in accordance with Art. 22 (3). The amendments to the transitional periods in accordance with Art. 120 only apply to "devices" of certain classes and therefore expressly not to sterile procedure packs. Accordingly, even in the case of (voluntary) extended surveillance, the natural or legal person placing sterile procedure packs on the market cannot assume that he can continue to claim the validity of the certificates issued under the 93/42/EEC.

With the above prerequisites and taking into account MDCG 2021-25, section 2 ("[...] *It appears logical to apply the transition period also to systems and procedure packs consisting only of 'legacy devices' and for which a declaration has been drawn up in accordance with the MDD prior to 26 May 2021.[...]*") **TÜV NORD CERT continues appropriate continued surveillance of sterile procedure packs based on valid contract with the natural or legal person placing sterile procedure packs on the market.**

List of sterile procedure packs covered by this letter:

Product name	Article number
Verbandset Nr. 2, steril	160002#
Verbandset, steril	160015#
Verbandset, steril	160016#
Vaginal-Set, steril	160025#
Notfall Desinfektionsset, steril	160029#
Verband-Set standard, steril	160030#
Verbands-Set, EOC, steril	160035#
Desinfektionsset vor OP Vers. 1, steril	160041#
Standard Set, steril	160043.2#
Desinfektionsset, steril	160044#
Putz Set, steril	160045#
Infiltrations Set, steril	160058#
Naht Set, steril	160060A#
Geburten Set, steril	160061A#
Nabel Set, steril	160062A#
Episiotomie Set, steril	160063A#
DK Set Urologie Amb., steril	160065#
Verband Set, steril	160067A#
DK Set, steril	160069#
Katheter Set für Dauerkatheter, steril	160072A#
Cystoskopie Set, steril	160073#
H.N.O Erstkonsultations-Set, steril	160076A#
Biopsie-Set Dermatologie, steril	160078A#
Multifunktions Set Universal V.2, steril	160080A#

Thorax Drainage Set, steril	160081A#
Versorgungs Set Zentrale Zugänge, steril	160083#
Wäschepaket Chir.Poliklinik V.3, steril	160086A#
Infiltrations Set, steril	160087A#
Verband Set Dermatologie, steril	160088A#
Pfleger Set, steril	160089A#
Herzpflege Set, steril	160090C#
Grosses Verband Set OIB, steril	160091#
Thorax Drainage Set RD, steril	160093A#
Boy-Set, steril	160096#
Zahnspiegel Set, steril	160097#
Fadenzieh Set, steril	160098#
Verbandsset für Katheter, steril	161083#
Katheterset per Fistel VOR, steril	161084#
Katheterset VOR/NACH, steril	161085#
Wunddesinfektionsset, steril	161090B#
H.N.O Epistaxis EW, steril	161252B#
Plastik-Beutel 20x30cm 50µm, steril	161410#
Set 1 K.S. Frauenfeld, steril	161413#
Set 2 K.S. Frauenfeld, steril	161414#
Katheterset, steril	161421.8#
Katheterset (mit Hibidil), steril	161421A#
SUVA Verband-Wechsel-Set A, steril	161422#
Katheterset Vers. I, steril	161425#
Katheterset Variante V, steril	161426.5A#
Portacath-Set, steril	161430#
Katheterset, steril	161432B#
ZVK-Set für Onkologie, steril	161453A#
Basis Verbands Set, steril	161468#
Set Kompressen Chirurgie, steril	161489#
Grosses Naht-Set, steril	161493A#
Geburten Set, steril	161494.2#
Pack Injection, steril	161498#
Set Suture HRC Vers.02	161506#
Fadenentfernungsset, steril	161509#
Naht-Set, steril	161510#
Putz-Set/Desinfektions Set gross, steril	161512A#
Verbandset mittel, steril	161514#
Fadenentfernungsset, steril	161516#
Kompressen-Set, steril	161523#
Behandlungseinheit, steril	161524.6#
Putz-Set, steril	161531.1#
Desinfektions-Set vor OP, stérile	161531.9#
Desinfektions-Set vor OP, stérile	161531.9A#
Putz-Set, steril	161531#
Dialyse Set, steril	161535.1A#
Lochtuch Set Dr. Thurnherr, steril	161539A#
Desinfektions-Set, Steril	161542#
Wundversorgungs-Set NFA, steril	161549.1A#
Wundversorgungs-Set NFA, steril	161549#
Stockinette, steril	161552.5#
Verbandset pro IDEAL-Econom, steril	161568#
WV-Set Einweginstrumente, steril	161579#
Katheter-Set II, steril	161582#
Wundversorgungs-Set, steril	161590#
Porth-à-Cath Set, steril	161592#
Cystoskopie Set REF 2, steril	161593#
Fadenset, steril	161596A#

Behandlungseinheit Arthro Set, steril	161616XC#
Set de base pour Soins-intensifs	161625#
Desinfektionsset, steril	161626#
Desinfektionsset (ohne Zange), steril	161627#
Behandlungseinheit Arthro-Set, steril	161632H#
Desinfektions Set klein, steril	161640#
Hüftpunktion Set, steril	161641A#
Kniepunktion Set, steril	161642A#
Punktionsset Portsyst., steril	161651#
Excision Set (Derma), steril	161652A#
Arthro Set HR, steril	161653A#
Behandlungseinheit Intervention 3, steril	161654B#
Hand-Set, steril	161655C#
Hand-Set, steril	161655D#
Universal Set, steril	161659B#
Schlitztuch Set ORL, steril	161662B#
Putz-Set ORL, steril	161671#
Behandlungseinheit Intervention, steril	161674D#
Verbandset, steril	161698A#
OP Set, steril	161701A#
Behandlungseinheit Infiltration, steril	161706C#
Zellstoffwattetupfer-Set klein, steril	161715#
Fadenentfernungs-Set klein, steril	161738#
Fadenset, steril	161739#
Phlebographie Set, steril	161743A#
Behandlungseinheit Biopsie, steril	161748A#
Stereotaxie-Set, steril	161797A#
Endoskopie Pack HFR, steril	161808#
Vorbereitungsset für Anästhesie, steril	161809#
Mehrzweck Punktions Set, steril	161810.5#
ZVK-Set, steril	161811D#
Behandlungseinheit (o. Medik.), steril	161813.1#
Lokale Anästhesie Set, steril	161814#
Infiltrationsset, steril	161815.1A#
Sakral Set, steril	161815.2A#
Behandlungseinheit (o. Medik.), steril	161816.1A#
ZVK Set, steril	161818A#
Set für pädiatrische Onkologie, steril	161819#
Behandlungseinheit Vers. 2, steril	161822#
Punktion-Set, steril	161823#
Punktionsset Ovarialzyste Vers.II, steril	161825#
Lumbal Punktions Set, steril	161826#
Kathetereinführungs Set, steril	161832A#
Urethrotomie Set	161833#
Cystostomie Wechsel Set, steril	161834A#
Bronchoskopie Set, steril	161835.1A#
Bronchoskopie Set, steril	161835.2#
Bronchoskopie Set, steril	161835A#
Blasenkatheter Set (Kinder), steril	161850A#
Blasenspülset, steril	161853A#
Bülau Set, steril	161855A#
Dialyse Set Vor / Nach, steril	161992#
Dialyse Set Branchment p. Fistule, steril	161997.2#
Dialyse Verband Set für Hämodialyse	161999.1#
Dialyse Verband Set auf Katheter	161999#
Scharfer Löffel Set, steril	162131.1#
Scharfer Löffel Set Volkmann, steril	162133.1#
Bauchstraffungs und Brust Pack, steril	162355#

Mamma Pack, steril	162538C#
Behandlungseinheit, steril	162562.3B#
Pack PTG	162592.1#
Behandlungseinheit, steril	162603.4C#
Trousse Epaule vers.2	162603.6#
Thorax Drainage Kit, steril	162609#
Hand Set, steril	162610C#
Schulterarthroskopie-Pack V.2, steril	162617#
Hüft Pack MIC, steril	162634A#
Urologie Set klein Vers. II, steril	162640#
Behandlungseinheit Universal Set, steril	162644A#
Kreuzband Set, steril	162652C#
Pack Milligan Morgan, steril	162660B#
Hüft-Pack MIC, steril	162666A#
Vasektomie Set Vers. 2, steril	162680.1#
Vasektomie Set Vers. 3, steril	162680#
Circumcision Set, steril	162681.1#
Circumcision Set Vers. 2, steril	162681#
Geburten Set, steril	162688A#
Naht Set Vers. A, steril	162689A#
Geburten-Set, steril	162691B#
Naht-Set, steril	162692#
Pädiatrie Universal Pack, steril	162702.5B#
Behandlungseinheit Hand-Set, steril	162703.1E#
RTU Pack, steril	162705C#
Arthroskopie-Set, steril	162710.1B#
Bypass Pack, steril	162711.1A#
Set Episiotomie	162713#
Geburten Set EOC, steril	162714#
Gyn-Set, steril	162728E#
Onkologische Behandlungseinheit, steril	162730#
Behandlungseinheit Angio, steril	162738B#
Zirkumzision Set, steril	162739C#
Knie Arthroskopie Pack, steril	162772E#
Arthroskopie Knie Pack, steril	162895.1A#
Wirbelsäule Pack, steril	162917#
Laparoskopie Pack Da Vinci/Gynèc, steril	162921.1A#
Da Vinci Pack, steril	162921B#
Kleines Pack, steril	162927A#
Cardio Pack, steril	162934E#
Labioplastik-Set, steril	162938M#
Wundversorgungs-Set, steril	162946B#
Universalabdecktuch 98x158cm, steril	162969.3#
OTR-Pack CHUV, steril	163020#
Hand Pack Vers.2, steril	163021A#
Fuss-Knöchel Pack, steril	163026A#
Set Gripper/Onkologie, steril	163027#
Set mit Instrumenten, steril	163061#
Komplementär-Pack vertikal, steril	163069#
Wasch Set HRC, steril	163071#
Nierenschale Set, steril	163072#
Basis Pack vertikal, steril	163076#
Set Schalen, steril	163077A#
Prä-OP Desinfektionsset SZO, steril	163079#
Wundversorgungsset, steril	163080#
Verbandswechselset, steril	163081#
Ernährungsset Pädiatrie, steril	163082#
Ernährungsset Pädiatrie, steril	163083#

Gynäkologie-Set, steril	163084#
Vaginal-Waschset, steril	163085#
Dialyse Set auf Katheter, steril	163086#
Dialyse-Anschluss Set, steril	163087#
Ernährungsset Pädiatrie HRC, steril	163088#
Broncho Set, steril	163142A#
Gastro-Koloskopie Set, steril	163143B#
ORL Basis Set, steril	163144#
Blutkultur-Set, steril	163146B#
U-Tuch Pack Gross, steril	163164#
Set Schalen, steril	163190B#
Port a Cath Set Vers. 3 ,steril	163204#
Verband Set, steril	163252#
Zungenbandset, steril	163269#
Geburtenset, steril	163270C#
Naht Set, steril	163271B#
Nabel Set, steril	163272A#
Arthroskopie Binden Set, steril	163273#
Binden Set gross, steril	163274#
Varizen Binden Set, steril	163275#
Tracheotomie Pflege-Set, steril	163299#
Schulter Arthroskopie Pack, steril	163300#
Schulter Pack (offener Eingriff), steril	163301#
Hand Pack (kleiner Eingriff), steril	163302A#
Orthopädie Pack, steril	163304B#
Katheter Set Vers.III, steril	163318A#
Desinfektionsset, steril	163325#
Punktionssset, steril	163329B#
Venenkatheter Set, steril	163337A#
Geburten Set Instrumente, steril	163343#
Geburten Set Faden, steril	163344#
Schulter Pack, steril	163345B#
Set Rundschale 2500ml + Wattekugeln	163346A#
Fadenentfernungsset, steril	163347#
Grosses Desinfektionsset, steril	163349#
Set Radiologie, steril	163350A#
Gripperset HVS-Valais, steril	163351#
PNL Zusatz Set Urologie, steril	163390A#
Konversion Viszeral Set, steril	163392#
Gefäss abdominal-Pack, steril	163395I#
Extensions-Pack, steril	163397A#
ASK-Pack, steril	163398A#
Bohrloch-Pack, steril	163399C#
TEA Carotis/Bypass Pack, steril	163408E#
Laparoskopie-Pack Beinlinge, steril	163412B#
Laparoskopie-Pack Universal, steril	163413B#
Minimalinvasiv-Pack, steril	163414C#
ASK Schulter-Pack, steril	163420B#
Universaltuch-Pack klein, steril	163421A#
Thorakoskopie-Pack, steril	163424E#
Laparotomie-Pack Universal, steril	163426D#
Laparotomie-Pack Beinlinge, steril	163427C#
Rundschalen-Tupfer Set, steril	163431#
Kleines Pack mit U-Tuch, steril	163438A#
Gastro Kit, steril	163447A#
Kompressen Set für Kaiserschnitt, steril	163451B#
Cystoskopie Set, steril	163463#
Allgemein Set, steril	163490C#

Behandlungseinheit kleines chirurgisches	163491A#
Wundversorgungsset, steril	163551B#
Basic Set, steril	163600#
Rundschale mit Wattekugeln, steril	163601#
Deluxe Set Erweiterung, steril	163602A#
Gyni Putzset, steril	163632B#
WV-Set Einweginstrumente.,steril	163635A#
BCG / Mitem Set, steril	163636C#
Zystoskopie Set, steril	163638A#
UD Set, steril	163646C#
Zystofix-DK Set, steril	163647A#
Behandlungseinheit, steril	163685D#
Behandlungseinheit, steril	163686C#
Behandlungseinheit, steril	163687A#
Behandlungseinheit, steril	163689A#
Behandlungseinheit, steril	163690#
INP Wundversorgungs & Abwasch Set,steril	163710A#
WV Naht Set, steril	163800A#
Nahtset Anä/IB, steril	163801#
Kleines Chirurgie-Set, steril	165051#
Varizen Binden Set, dopp.verp., steril	165559#
Naht Set, steril	165562#
Nahtset für Cystofix, steril	165564#
Abdominalplastik Pack, steril	165569#
Infiltrationsset, steril	165573#
Verbandwechselset, steril	165574#
Konversionskit / Laparotomiekkit, steril	165575A#
Desinfektionsset, steril	165576B#
WV-Set fein, steril	165581B#
Dermatologie Set, steril	165583B#
OP Starter Kit Herz Chirurgie, steril	165586A#
Behandlungseinheit Punktion Set, sterile	165589#
Behandlungseinheit Fadenentfernungsset	165590#
Hüft-Pack MIC, steril	165591#
Fuss MICA Set, steril	165600B#
Grosses Naht-Set, steril	165603#
Universal Set, steril	165605B#
Beschneidungsset, steril	165621#
Y-Universalverbinder, steril	170025#
Sicherheitsnadel Grösse 3, steril	170039.9#
Rundschale 6L+Abdecktuch 112x150cm blau	170088.2#
Rundschale 6L+ Abdecktuch 112x150cm,blau	170088.3#
Schale mit Kompressen, steril	170100#
Rundschale-Kompressen-Set B, steril	170101.2#
Schalenset, weiss, dopp.verp, steril	170111.2#
Schalenset weiss, dopp.verp, steril	170112.2#
Schalenset weiss, dopp.verp,steril	170113.2#
Einweg Absaugung ELLIK, dopp.verp,steril	170119.1#
ORL-Pack, steril	2100000001#
Arthroskopie Knie Pack, steril	2100000011#
Hüft-Arthroskopie Pack, steril	2100000020#
Kniearthroskopie-Pack, steril	2100000030#
Laparotomie-Pack Universal, steril	2100000100#
Schulterarthroskopie-Pack V.2, steril	2100000110#
OPS-Abwaschset, steril	2100000130#
Lap PAC Gyn, steril	2100000140#
Thorakotomie Pack, steril	2100000150#
Behandlungseinheit, steril	2100000160#

Robotik-Set, steril	2100000170#
Sectio Pack, steril	2100000190#
Lappen Pack gross, steril	2100000200#
Vaginal Set klein, steril	2100000210#
Set für kleine Eingriffe, steril	2100000220#
MAP-Set, steril	2100000230#
Extremitäten-Set, steril	2100000240#
Wunddesinfektionsset, steril	2100000250#
Hand-Set, steril	2100000260#
Mini Set, steril	2100000270#
Hysteroskopie Pack, steril	2100000280#
Unfall-Ortho Pack klein, steril	2100000290#
Konversionskit / Laparotomiekit, steril	2100000300#
MIC Abdecktuch-Set, steril	2100000310#
Desinfektions-Set, steril	2110000080#
Becheli-Sieb Set, steril	2110000090#
Katheterset Blase, steril	2110000100#
Naht Set, steril	2110000110#
BCG / Mitem Set, steril	2110000160#
US Mammo Biopsie Set, steril	2120000010#
Biopsie-Set, steril	2120000030#
Punktionsset, steril	2120000040#
Behandlungseinheit Arthro 1S, steril	2140000010#
Behandlungseinheit Arthro 1S, steril	2140000011#
Punktionsset Radiologie, steril	2140000020#
Katheterset, steril	2140000030#
Zellstoffwatte-Tupfer-Set, steril	27823.5#
Set Bipolar Pinzette 165mm, steril	72000.1#
Set Bipolar Pinzette 165mm, steril	72001.1#
Bipolar Set mit Kabel, steril	72010.1#
Set Bipolar Pinzette Jeweler #7, steril	72200.1#
Set Bipolar Pinzette gerade, steril	72220.2#
Set Augensalbenstäbchen, steril	73076#
Set Silikonschlauch + Konnektor, steril	82006.2A#
Set Silikonschlauch + Konnektor, steril	82007.2A#
Vertikaltuch 320x235cm, steril	99531.1#

On behalf of the Notified Body,

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