DECLARATION OF CONFORMITY

MANUFACTURER: PERGO MEDIKAL VE ILAÇ SAN. A.Ş
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SRN No: TR-MF-000020761
PRODUCT REF NO/PRODUCT NAME: Attachment of ANNEX I /SUCTION LINER SYSTEM
CLASSIFICATION: CLASS I RULE 2 *(According to 2017/745 (Annex VIII and Meddev 2.4/1(rev09), non-sterile without measuring function)*
CONFORMITY ASSESSMENT ROUTE: 2017/745 MDR ANNEX II and Annex III
INTENDED USE: The Disposable Suction System is used for hygienic suction of various fluids and / or secretion from patients during medical treatment. The suction system has no contact with the human body.
APPLICABLE HARMONIZED STANDARDS: EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 19011:2012, EN ISO 15223-1:2021, EN 1041:2008(A1:2014), EN ISO/IEC 17050-1:2010, EN ISO/IEC 17050-2:2005, 2011/2588, ASTM F1929-15:2015, ASTM F 1980-16:2016, ASTM D5276-98:2017, EN ISO 10079-1:2015, EN ISO 10079-3:2022, MEDDEV 2.7/1 Rev 4: 2016, MEDDEV 2.12/1 Rev8:2013, MEDDEV 2.12/2 Rev2:2012, MEDDEV 2.4/1: Rev9:2010, EN ISO 62366-1:2015
WE HEREBY DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL REGULATION 2017/745 MEDICAL DEVICE AND ALL RELEVANT HARMONIZED STANDARDS. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.
WE DECLARE THAT THESE PRODUCTS DO NOT CONTAIN HUMAN BLOOD AND ITS DERIVATIVES, ANIMAL-DERIVED TISSUES, PHTHALATES, MEDICINAL PRODUCTS (DRUG), LATEX, RADIOACTIVE SUBSTANCES AND ELECTROMAGNETIC WAVES AND ARE UNDER OUR SOLE RESPONSIBILITY.
START OF CE MARKING: MAY, 2021
PLACE, DATE OF ISSUE: İZMİR-TURKEY, 2026

SIGNATURE:

Pergo
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OZAN BARAN /GENERAL MANAGER

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ANNEX I – PRODUCT TYPES

No	Product Ref No	Basic UDI-DI	Product Name
1	FSL100E	8682952411176BQ	MED-FLEX Essential 1L Suction Liner
2	FSL200E	8682952411176BQ	MED-FLEX Essential 2L Suction Liner
3	FSL300E	8682952411176BQ	MED-FLEX Essential 3L Suction Liner
4	FSC1000	8682952411176BQ	MED-FLEX 1L Reusable Outer Canister
5	FSC2000	8682952411176BQ	MED-FLEX 2L Reusable Outer Canister
6	FSC3000	8682952411176BQ	MED-FLEX 3L Reusable Outer Canister
7	FSLTT	8682952411176BQ	MED-FLEX Essential Tandem tubing
8	FSCCLAMP	8682952411176BQ	MED-FLEX rail clam
9	FSL2000	8682952411176BQ	2L Flexible Suction Liner
10	FSL2000T	8682952411176BQ	2L Flexible Suction Liner With Tandem Tubing
11	FSCVLC	8682952411176BQ	MED-FLEX vacuum L connector
12	FSCVTC	8682952411176BQ	MED-FLEX vacuum T connector
13	FSCVLCOF	8682952411176BQ	MED-FLEX vacuum connector with ON/OFF valve
14	FSLPC	8682952411176BQ	MED-FLEX patient L connector

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15	FSCADAPT	8682952411176BQ	MED-FLEX adaptor
16	FSCWM	8682952411176BQ	MED-FLEX wall mount
17	FSL200S	8682952411176BQ	2L FLEXIBLE SUCTION LINER
18	FSL200T	8682952411176BQ	2L FLEXIBLE SUCTION LINER WITH TANDEM TUBING
19	FSCVTCOF	8682952411176BQ	MED-FLEX Vacuum T-Connector with ON/OFF valve
20	FSL200SPG	8682952411176BQ	MED-FLEX 2L Suction Liner With Filter (Pre-Gelled)
21	FSL100EPG	8682952411176BQ	MED-FLEX Essential 1L Suction Liner (Pre-Gelled)
22	FSL200EPG	8682952411176BQ	MED-FLEX Essential 2L Suction Liner (Pre-Gelled)
23	FSL300EPG	8682952411176BQ	MED-FLEX Essential 3L Suction Liner (Pre-Gelled)
24	FSL100EV	8682952411176BQ	MED-FLEX Essential 1L Suction Liner With Valve
25	FSL200EV	8682952411176BQ	MED-FLEX Essential 2L Suction Liner With Valve
26	FSL300EV	8682952411176BQ	MED-FLEX Essential 3L Suction Liner With Valve
27	FSL100EK	8682952411176BQ	MED-FLEX Essential 1L Liner with 6mm x 1.8m tubing
28	FSL200EK	8682952411176BQ	MED-FLEX Essential 2L Liner with 6mm x 1.8m tubing
29	FSL300EK	8682952411176BQ	MED-FLEX Essential 3L Liner with 6mm x 1.8m tubing

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30	MFSS7	8682952411176BQ	MFE Standard specimen sock 7mm x 23cm
31	MFSS10	8682952411176BQ	MFE Large specimen sock 10mm x 23cm
32	MFSA10	8682952411176BQ	MFE Sample Port large adaptor 10mm
33	FSCMCLAMP	8682952411176BQ	MED-FLEX Metallic Rail Clamp
34	FSCBB	8682952411176BQ	MED-FLEX Bed Bracket

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