# DECLARATION OF CONFORMITY

**MANUFACTURER:** PERGO MEDIKAL VE ILAÇ SAN. A.Ş
**ADDRESS:** BUCA OSB MAH. 2/20 SOK BEGOS SIT. NO:9 BUCA IZMIR TURKEY 35400
**CONTACT:** +90 232 290 8929 / info@pergomed.com
**MHRA Account Number:** 0000023161
**UK RESPONSIBLE PERSON:** CMC Medical Devices Ltd.
**UK RESPONSIBLE PERSON ADDRESS:** Office 32 19-21 Crawford Street, W1H 1PJ, London
**MHRA Account Number:** 0000010651
**PRODUCT REF NO/PRODUCT NAME:** Attachment of ANNEX I /SUCTION LINER SYSTEM
**CLASSIFICATION:** Class I self-certified
**CONFORMITY ASSESSMENT ROUTE:** Part II of the UK MDR 2002, Annex VII (as modified by Part II of Schedule 2A to the UK MDR 2002)
**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 10079-3:2014,
**WE HEREBY DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF THE Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) 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.**
**SIGNATURE:**

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Pergo Medikal ve İlaç Sanayi A.Ş.
Buca OSB Mh. 2/20 Sk. BEGOS Sit. No:9 Buca IZMIR
Sicil No: 072804035870001 5

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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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