carilex®

Carilex Medical, Inc.
No.77, Keji 1st Rd., Guishan Dist.,
Taoyuan City (333), Taiwan (R.O.C.)

EC Declaration of Conformity

Certificate No. DOC-S21021701

Product Name : Anti-decubitus devices, pumps, air flotation mattresses

Article Number:

S2809-3015	DomestiCare P.U. EU
S2809-2010	DomestiCare M-set 90x200cm TDX

Device Classification: Class I (in accordance with Annex VIII Rule 13 of Medical Device Regulation(EU)2017/745) as amended by Regulation (EU) 2020/561

Manufacturer: Carilex Medical, Inc.
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European Representative: Carilex Medical B.V
Zekeringstraat 41D, 1014BV Amsterdam, Netherlands

Harmonized Standard(s) to which Conformity is Declared:

- EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes
- EN ISO 14971:2012 Medical devices - Application of risk management to medical devices.
- EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- EN 1041:2008 Information supplied by the manufacturer of medical devices
- EN 60601-1:2006 Medical electrical equipment-
  Part 1: General requirement for basic safety and essential performance
- EN 60601-1-2:2007 Medical electrical equipment-
  Part 1- 2: General requirements for basic safety and essential performance.
  Collateral standard: Electromagnetic disturbances – Requirements and tests
- EN 62366:2008 Medical devices - Application of usability engineering to medical devices
- EN 62304:2006 Medical device software - Software life-cycle processes

Carilex Medical, Inc. declares that the products described herein comply with the requirements set out in the European Parliament and the Council on the harmonization of the Laws of the Member States concerning **Medical Device Regulation (EU) 2017/745** as amended by Regulation (EU) 2020/561 and meet all the applicable general safety and performance requirement in Annex I of the Medical Device Regulation. Carilex Medical, Inc. has the sole responsibility on the products are manufactured, inspected, tested, and released according to the approved quality assurance system established in accordance with EN ISO 13485:2016 and EU Declaration of Conformity of Annex IV of Medical Device Regulation (EU) 2017/745 as amended by Regulation (EU) 2020/561.

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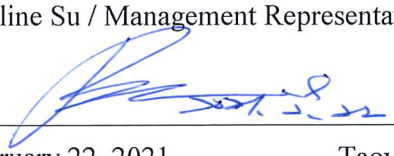
Issued by

Pauline Su / Management Representative



February 22, 2021 Taoyuan