carilex®

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

Declaration of Conformity

Certificate No. DOC-S15082701

Product Name : Air flotation mattress for decubitus ulcers (bed sores) treatment

Model/Article Number:
DualPlus System S2102-0XXX: DualPlus Power Unit S2102-3065/DualPlus Mattress S2102-2XXX
Dual GT System S2103-0XXX: Dual GT Power Unit S2103-3035/Dual GT Mattress S2103-2XXX
RevoPlus System S2205-0XXX: RevoPlus Power Unit S2205-3025/ RevoPlus Mattress S2205-2XXX
Entrix System S2202-0XXX: Entrix Power Unit S2202-3115/Entrix Mattress S2202-2XXX
Entrix MR System S2202-0CXX: Entrix Power Unit S2202-3115/Entrix MR Mattress S2202-2XXX
DualPlus-R System S2102-0CXX: DualPlus Power Unit S2102-3065/RevoPlus Mattress S2205-2XXX
RevoPlus-D System S2205-0CXX: RevoPlus Power Unit S2205-3025/DualPlus Mattress S2102-2XXX
Coziny 100 System S2302-0045: Coziny 100 Power Unit S2302-3045/Coziny 100 Mattress S2302-2010
Coziny 200 System S2302-0055: Coziny 200 Power Unit S2302-3055/Coziny 200 Mattress S2302-2020
Coziny 300 System S2302-0065: Coziny 300 Power Unit S2302-3065/Coziny 300 Mattress S2302-2030
TheraFlo AP System S2002-0XXX: TheraFlo AP Power Unit S2002-3055/TheraF Mattress S2001-2XXX
AirMax Mattress S2204-2XXX

Device Classification: Class IIa

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

European Representative: Carilex Medical GmbH
Turmbergstr, 9A D-76227 Karlsruhe, Germany

Reference Standard(s) to which Conformity is Declared:

EN60601-1 / EN60601-1-2 / EN IEC 62304:2006 / EN 60601-1-6:2010 / EN 61000-3-2: 2005/A1: 2008/A2: 2009 / EN61000-3-3:2008 / EN15233:2012 / ISO13485: 2003 / EN ISO14971: 2012

Carilex Medical, Inc. declares that the products described herein meet all the applicable Essential Requirements of the Medical Device Directive of the European Union 93/42/EEC in Annex I.
The product is manufactured, inspected, tested, and released in accordance with the approved quality assurance system established in accordance with ISO 13485:2003 and Annex II (exclude section 4) of the Medical Device Directive of the European Union under the supervision of SGS United Kingdom, a Notified Body carrying the Notified Body No.0120.

Issued by
Pauline Su / Management Representative

August 27, 2015