CORITON

Declaration of Conformity

Document No.: 2020.06_DC_EN

Manufacturer:

CORITON INSTRUMENT CO., LTD

5F Building C, Gold Power Industry Park,Julongshan Grand industrial Zone,

Pingshan Dist.,Shenzhen, China 518118

Global Location Number (GLN) : 69734 56940 012

ISO9001 No.: TUV100043378

FDA registration No.: 3013182765

EU Representative:

Umedwings Netherlands B.V.

Radonstraat 28, 2718TA Zoetermeer, The Netherlands

service@umedwings.com

Products :

Medical trolley ,wall mount and support arm.

(Types and order numbers see appendix 1)

According to the Council Regulation (EU) MDR 2017/745, Annex VII Chapter III,4.1 all CORITON products are defined as non sterile and non invasive medical devices and assigned to class I .

CORITON hereby declares the product mentioned in following appendix 1 is in conformity, complies with the following standard or normative document:

IEC 60601-1:2005 + Cor.:2006 + Cor.:2007 + A1:2012

EN 60601-1:2006 + Cor.:2010 + A1:2013

and is in accordance with the provisions of the relevant specific regulation(s) for medical devices 2017/745 Appendix IX. The compliance with the 2011/65/EC (RoHS) directive on the restriction of use of certain hazardous substances in electrical and electronic equipment is hereby confirmed.

Note: This declaration loses its validity by not normal use and by changes to the medical device which are not agreed with the manufacturer.

Products and kit may include non-medical accessories.

UDI / EUDAMED is currently not available.

This declaration does not contain any assurance of product attributes based on the product-liability-law.

Place, date of issue:

CORITON INSTRUMENT CO., LTD.

Shenzhen China June 5th 2020

Haoliang Chen, Quality Dept Manager

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Appendix 1

Type Reference	Description
TR900-XXX-XXX	Endoscopy/ medical Cart
TR800-XXX-XXX	Computer / medical Cart
TR700-XXX-XXX	Computer / medical Cart
RS011-XXX-XXX	Roll Stand
RS010-XXX-XXX	Roll Stand
RS002-XXX-XXX	Roll Stand
RS001E-XXX-XXX	Roll Stand
RS001C-XXX-XXX	Roll Stand
RS001-XXX-XXX	Roll Stand
WM500-XXX-XXX	Wall mount
WM001E-XXX-XXX	Wall mount
WM001-XXX-XXX	Wall mount
AR10X-XXX-XXX	Support Arm

X stand for any letter or number.

Attention: To fulfill the safety requirements for CORITON products, please observe that all information shown in the operating manual must be fulfilled, before installation of devices as well as for the later addition of accessories.