

EC Declaration of Conformity

Manufacturers Name:	Soteria Medical B.V.
Manufacturers Address:	Meander 251, 6825 MC Arnhem, The Netherlands
SRN (Single Registration Number):	NL-MF-000005744
Basic UDI-DI:	8719326662008
Name of the Device(s):	Remote Controlled Manipulator
Product Code:	10 100
Classification:	I
Conformity Assessment Route:	Annex II and Annex III, Technical documentation in combination with Annex IV, EU declaration of Conformity of Regulation (EU) 2017/745

This declaration of conformity is issued under the sole responsibility of Soteria Medical B.V.

We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices,

and are in conformity with the relevant harmonized standards EN 1041:2008, EN ISO 10993-1:2020, EN ISO 14155:2011, EN ISO 14971, EN ISO 15223-1: 2016, EN ISO 60601-1:2015, EN ISO 60601-1-6:2010, EN 62304:2006, EN 62366:2015 and ASTM F2503-20

And are in conformity with Directive 2011/65/EU as amended by directive (EU) 2015/863 (RoHS), Directive 2014/30/EC (EMC), Directive 2012/19/EU (WEEE).

This declaration is supported by the Quality System approval to ISO 13485:2016 issued by DEKRA, Certificate #2180714. All supporting documentation is retained at the premises of the manufacturer.

Signature:

Date(yyyy.mm.dd) and place of issue :



2021.06.01 Arnhem

Jan Sabisch,
Chief Executive Officer Soteria Medical B.V