

Concept Medical

EC DECLARATION OF CONFORMITY

Name of Manufacturer: Concept Medical B.V.

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Product Name: **Magic Touch SCB - Sirolimus Coated Balloon Catheter**
Batch / Lot No: _____ Manufacturing Date: _____
Batch / Lot Size: _____ Expiry Date: _____
Release Quantity: _____

Product Classification: **Class III** as per the applicable classification rules for Drug Coated Balloon Catheter Annex IX, Chapter III, Section 4.1 (rule 13) of the MDD 93/42/EEC amended by 2007/47/EC.

Product Conformity Route: Annex II (Full Quality Assurance) including Section 4 of Medical Directive MDD 93/42/EEC amended by 2007/47/EC. We herewith declare that above mentioned product meet the provisions of the council directive 93/42/EEC amended by 2007/47/EC for medical devices. All supporting documentation is retained at the premises of the manufacturer.

Standards applied: MDD 93/42/EEC as amended by 2007/47/EC, EN ISO 15223-1:2021, EN ISO 10993-1:2009, EN ISO 10993-1:2009/AC:2010, EN ISO 10993-3:2014, EN ISO 10993-4:2009, EN ISO 10993-5:2009, EN ISO 10993-6:2009, EN ISO 10993-7:2008, EN ISO 10993-7:2008/AC:2009, EN ISO 10993-11:2018, EN ISO 10993-12:2021, EN ISO 10993-18:2020, EN ISO 10993-23:2021, EN ISO 13485:2016, EN ISO 13485:2016/A11:2021, EN ISO 13485:2016/AC:2018, EN ISO 10555-1:2009, EN ISO 11135:2014, EN ISO 11135:2014/A1:2019, EN ISO 11140-1:2009, EN ISO 11138-2:2009, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 14971:2019, EN ISO 14971:2019/A11:2021, EN ISO 14155:2020, EN ISO 1041:2008, EN ISO 11737-1:2018, EN ISO 11737-1:2018/A1:2021, EN ISO 11737-2:2020.

Notified Body: POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A., NB No. 1434

EC Certificate: EC Certificate No.: 1434-MDD-492/2019; Issued on: 16/10/2019; Valid until: 27/05/2024 & EC Design Examination Certificate No.: 1434-MDD-491/2019; Issued on: 16/10/2019; Valid until: 27/05/2024.

Signature:

Name and Designation:

Place: The Netherlands

Date of Issue: DD/MM/YY

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