

## EC DECLARATION OF CONFORMITY

**Name of Manufacturer:** Concept Medical B.V.

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**Administration Address:** Dashorsterweg 8a  
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**Product Name:** **Magic Touch PTA – Sirolimus Coated PTA Balloon Catheter (0.014", 0.018" & 0.035" OTW)**  
Batch / Lot No: \_\_\_\_\_ - \_\_\_\_\_ Manufacturing Date: \_\_\_\_\_ - \_\_\_\_\_  
Batch / Lot Size: \_\_\_\_\_ - \_\_\_\_\_ Expiry Date: \_\_\_\_\_ - \_\_\_\_\_

**Product Classification:** **Class III** as per the applicable classification rules for Drug Coated PTA 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 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 /AC:2009, EN ISO 10993-11:2018, EN ISO 10993-12:2012, EN ISO 14155:2011 /AC:2011, EN ISO 15223-1:2016, EN 1041:2008, EN ISO 11135-1:2007, EN ISO 14971:2012, EN ISO 13485:2016/AC:2018, EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 11737-1:2006 /AC:2009, EN 1707:1996, EN ISO 10555-1:2009, EN ISO 11140-1:2009, EN ISO 11138-2:2009

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

**EC Certificate:** EC Certificate No.: 1434-MDD-221/2020; Issued on: 27/05/2020; Valid up to: 27/05/2024 & EC Design Examination Certificate No.: 1434-MDD-220/2020; Issued on: 27/05/2020; Valid up to: 27/05/2024.

**Signature:** \_\_\_\_\_

**Name and Designation:** \_\_\_\_\_

**Place:** The Netherlands **Date of Issue:** 02/09/2020

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