



# CERTIFICATE

**EC Certificate No. 1434-MDD-491/2019**  
**EC Design-examination**

**Directive 93/42/EEC concerning medical devices**

Polish Centre for Testing and Certification certifies  
that the documentation submitted by:

**Concept Medical B.V.**

**Hogebrinkerweg 33, 3871 KM Hoevelaken**  
**The Netherlands**

related to the medical device, class III

**Sirolimus Coated Balloon Catheter**  
**MagicTouch - SCB**

*The list of medical devices covered by this certificate is given in the Annex No. 1 to the Certificate*

was examined in accordance with Annex II (Section 4) to Directive 93/42/EEC (as amended by 2007/47/EC)  
implemented into Polish law, as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 2019-10-16 to 2024-05-27

The date of issue of the Certificate: 2019-10-16



Application No: 005/2019  
Module H



Certificate No. **1434-MDD-491/2019**  
Issued under the Contract No. **MD-09/2019**  
Bears the PCBC hologram  
Warsaw, 16/10//2019



**ANNEX 1 TO CERTIFICATE**  
**VALID ONLY WITH CERTIFICATE**  
**No 1434-MDD-491/2019**

**Sirolimus Coated Balloon Catheter**

**Brand Name: MagicTouch – SCB**

Balloon Diameter (mm)	Balloon Length(mm)						
	10	15	20	25	30	35	40
1.50	CMN15010	CMN15015	CMN15020	CMN15025	CMN15030	CMN15035	CMN15040
2.00	CMN20010	CMN20015	CMN20020	CMN20025	CMN20030	CMN20035	CMN20040
2.25	CMN22510	CMN22515	CMN22520	CMN22525	CMN22530	CMN22535	CMN22540
2.50	CMN25010	CMN25015	CMN25020	CMN25025	CMN25030	CMN25035	CMN25040
2.75	CMN27510	CMN27515	CMN27520	CMN27525	CMN27530	CMN27535	CMN27540
3.00	CMN30010	CMN30015	CMN30020	CMN30025	CMN30030	CMN30035	CMN30040
3.25	CMN32510	CMN32515	CMN32520	CMN32525	CMN32530	CMN32535	CMN32540
3.50	CMN35010	CMN35015	CMN35020	CMN35025	CMN35030	CMN35035	CMN35040
4.00	CMN40010	CMN40015	CMN40020	CMN40025	CMN40030	CMN40035	CMN40040





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