



CERTIFICATE

EC Certificate No. 1434-MDD-492/2019
Full Quality Assurance System

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Concept Medical B.V.

Hogebrinkerweg 33, 3871 KM Hoevelaken
The Netherlands

for the design, manufacture and final inspection of
medical devices, class III

Sirolimus Coated Balloon Catheter
MagicTouch - SCB

complies with requirements
of Annex II (excluding 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-492/2019**
Issued under the Contract No. **MD-09/2019**
Bears the PCBC hologram
Warsaw, 16/10//2019