



CERTIFICATE

EC Certificate No. 1434-MDD-221/2020
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 PTA Balloon Catheter
Brand name: Magic Touch PTA

The list of medical devices covered by this certificate is provided in the annex 1 to EC Design-examination Certificate No. 1434-MDD-220/2020

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 2020-05-27 to 2024-05-27

The date of issue of the Certificate: 2020-05-27

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



Issued under the Contract No. **MD-09/2019**
Application No: **082/2020**
Certificate bears the qualified signature.
Warsaw, 27/05/2020
Module H

