

EC Certificate No. 1434-MDD-033/2020 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:

EUROCOR Tech GmbH

In den Dauen 6a, 53117 Bonn, Germany

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

Paclitaxel eluting PTA balloon catheter FREEWAY™ 035

List of medical devices covered by this certificate is given in the Annex no. 1, 2, 3, 4 and 5 to the EC-Design-examination Certificate No. 1434-MDD-034/2020

> complies with requirements of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended) implemented into Polish law,

> > as evidenced by the audit conducted by the PCBC

Validity of Certificate: from 2020-02-06 to 2024-05-27

The date of issue of the Certificate: 2020-02-06 The date of the first issue of the Certificate: 2007-07-10

 CE_{442}

Application No: 333/2019

Module: H2



Certificate No 1434-MDD-033/2020 Issued under the Contract No MD-214/2019 Bears the PCBC hologram. Warsaw, 2020/02/06