

EC Certificate No. 1434-MDD-032/2020 EC Design-Examination

Directive 93/42/EEC concerning medical devices

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

EUROCOR Tech GmbH

In den Dauen 6a, 53117 Bonn, Germany

related to the medical device

DIOR Paclitaxel eluting PTCA balloon catheter

List of medical devices covered by this certificate is given in the Annex no. 1

was examined in accordance with Annex II (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: 2007-02-06



Application No: 332/2019

Module: H1

mgr Anna Wyroba Vice-President



Certificate No 1434-MDD-032/2020 Issued under the Contract No MD-214/2019 Bears the PCBC hologram. Warsaw, 2020/02/06



ANNEX NO. 1 TO CERTIFICATE

VALID ONLY WITH CERTIFICATE No 1434-MDD-032/2020

The product detailed below are covered under the scope of this certificate:

Balloon diameter (mm)	Balloon length (mm)			
	15	20	25	30
2.00	DIOR 2.00-15	DIOR 2.00-20	DIOR 2.00-25	DIOR 2.00-30
2.25	DIOR 2.25-15	DIOR 2.25-20	DIOR 2.25-25	DIOR 2.25-30
2.50	DIOR 2.50-15	DIOR 2.50-20	DIOR 2.50-25	DIOR 2.50-30
2.75	DIOR 2.75-15	DIOR 2.75-20	DIOR 2.75-25	DIOR 2.75-30
3.00	DIOR 3.00-15	DIOR 3.00-20	DIOR 3.00-25	DIOR 3.00-30
3.50	DIOR 3.50-15	DIOR 3.50-20	DIOR 3.50-25	DIOR 3.50-30
4.00	DIOR 4.00-15	DIOR 4.00-20	DIOR 4.00-25	DIOR 4.00-30







Annex no. 1 to certificate No. **1434-MDD-032/2020** Issued under the Contract No. MD-214/2019 Bears the PCBC hologram.
Warsaw, 2020/02/06