Eurocor

Declaration of Conformity

Name and address of the Manufacturer:

Eurocor Tech GmbH
In den Dauen 6a
53117 Bonn
Germany

We declare under our sole responsibility that the medical device

Paclitaxel eluting PTA balloon catheter FREEWAY™ 035
(as defined in the annex)

Classified as follows according to the directive on medical devices 93/42/ECC:
Class III Product

Catheter: Class III under Annex IX Rule 6/13

These devices meet the requirements of Annex I and II (including section 3 and 4) Directive 93/42/ECC.

Conformity assessment procedure:	Annex II
Certificate No.	1434-MDD-033/2020 1434-MDD-034/2020
Notified Body:	PCBC S.A. ul. Puławska 469 02-844 Warsaw Poland
Notified Body No.:	1434

Eurocor Tech GmbH
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53117 Bonn - Germany
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Bonn, 01.09.2020

Place and date of issue

Vivek Ramnani
Managing Director

ANNEX I TO DECLARATION OF CONFORMITY

Paclitaxel eluting PTA balloon catheter FREEWAY™ 035
(Class III Product)

Balloon Size		Order Number	Shaft length
Diameter (mm)	Length (mm)	FREEWAY™ 035	S (short) 80 cm
4	20	335-4020 S	S
4	40	335-4040 S	S
4	60	335-4060 S	S
4	80	335-4080 S	S
4	100	335-40100 S	S
4	120	335-40120 S	S
4	150	335-40150 S	S
4	190	335-40190 S	S
4	230	335-40230 S	S
5	20	335-5020 S	S
5	40	335-5040 S	S
5	60	335-5060 S	S
5	80	335-5080 S	S
5	100	335-50100 S	S
5	120	335-50120 S	S
5	150	335-50150 S	S
5	190	335-50190 S	S
5	230	335-50230 S	S
6	20	335-6020 S	S
6	40	335-6040 S	S
6	60	335-6060 S	S
6	80	335-6080 S	S
6	100	335-60100 S	S
6	120	335-60120 S	S
6	150	335-60150 S	S
6	190	335-60190 S	S
6	230	335-60230 S	S
7	20	335-7020 S	S
7	40	335-7040 S	S
7	60	335-7060 S	S
7	80	335-7080 S	S
7	100	335-70100 S	S
7	120	335-70120 S	S
7	150	335-70150 S	S
7	190	335-70190 S	S
7	230	335-70230 S	S
8	20	335-8020 S	S
8	40	335-8040 S	S
8	60	335-8060 S	S
8	80	335-8080 S	S
8	100	335-80100 S	S

Balloon size		Order number	Shaft length
Diameter (mm)	Length (mm)	FREEWAY™ 035	L (long) 135 cm
4	20	335-4020 L	L
4	40	335-4040 L	L
4	60	335-4060 L	L
4	80	335-4080 L	L
4	100	335-40100 L	L
4	120	335-40120 L	L
4	150	335-40150 L	L
4	190	335-40190 L	L
4	230	335-40230 L	L
5	20	335-5020 L	L
5	40	335-5040 L	L
5	60	335-5060 L	L
5	80	335-5080 L	L
5	100	335-50100 L	L
5	120	335-50120 L	L
5	150	335-50150 L	L
5	190	335-50190 L	L
5	230	335-50230 L	L
6	20	335-6020 L	L
6	40	335-6040 L	L
6	60	335-6060 L	L
6	80	335-6080 L	L
6	100	335-60100 L	L
6	120	335-60120 L	L
6	150	335-60150 L	L
6	190	335-60190 L	L
6	230	335-60230 L	L
7	20	335-7020 L	L
7	40	335-7040 L	L
7	60	335-7060 L	L
7	80	335-7080 L	L
7	100	335-70100 L	L
7	120	335-70120 L	L
7	150	335-70150 L	L
7	190	335-70190 L	L
7	230	335-70230 L	L
8	20	335-8020 L	L
8	40	335-8040 L	L
8	60	335-8060 L	L
8	80	335-8080 L	L
8	100	335-80100 L	L

Paclitaxel eluting SHUNT balloon catheter FREEWAY™ 035
(Class III Product)

Balloon Size		Order Number	Shaft Length
Diameter (mm)	Length (mm)	FREEWAY™ 035	AV (Shunt) 40 cm
4	20	335-4020 AV	AV
4	40	335-4040 AV	AV
4	60	335-4060 AV	AV
5	20	335-5020 AV	AV
5	40	335-5040 AV	AV
5	60	335-5060 AV	AV
6	20	335-6020 AV	AV
6	40	335-6040 AV	AV
6	60	355-6060 AV	AV
7	20	335-7020 AV	AV
7	40	335-7040 AV	AV
7	60	335-7060 AV	AV
8	20	335-8020 AV	AV
8	40	335-8040 AV	AV
8	60	335-8060 AV	AV

ANNEX II TO DECLARATION OF CONFORMITY

Norms and Applicable Standards

ASTM D 4169:2016
Standard practice for shipping, containers and systems

ASTM D 4332:2014
Standard practice for conditioning containers, packages or packaging components for testing

ASTM F 88/ 88 M:2015
Standard test method for seal strength of flexible barrier materials

ASTM F 756-17
Standard practice for assessment of hemolytic properties of materials

ASTM F 1929-15
Standard test method for detect seal leaks in porous medical packaging by dye penetration

ASTM F 1980 – 16
Standard guide for accelerated aging of sterile barrier systems for medical devices

AAMI TIR28:2016
Product adoption and process equivalence for ethylene oxide sterilization

DIN EN 556-1:2002 / AC:2006
Sterilization of medical devices – Requirements for medical devices to be designated "STERILE" – Part 1: Requirement for terminally sterilized medical devices

DIN EN ISO 80369-7:2017
Small bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications

DIN EN 868-2:2017
Packaging for terminally sterilized medical devices Part 2: Sterilization wrap – Requirements and test methods

DIN EN ISO 15223-1:2017
Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements

DIN EN 1041:2013
Information supplied by the manufacturer of medical devices

DIN EN 1422:2014
Sterilizers for medical purposes – Ethylene oxide sterilizers - Requirements and test methods

DIN EN ISO 10555-1:2018
Intravascular catheters – Sterile and single-use catheters – Part 1: General requirements

DIN EN ISO 10555-4:2013

Intravascular catheters – Sterile and single-use catheters Part 4: Balloon dilatation catheters

DIN EN ISO 10993-1:2010
Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management system

DIN EN ISO 10993-4:2017
Biological evaluation of medical devices – Part 4: Selection of tests for interaction with blood

DIN EN ISO 10993-5:2009
Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity

DIN EN ISO 10993-7:2009
Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals

DIN EN ISO 10993-10:2014
Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

DIN EN ISO 10993-11:2009
Biological evaluation of medical devices – Part 11: Tests for systemic toxicity

DIN EN ISO 10993-12:2012
Biological evaluation of medical devices – Part 12: Sample preparation and reference materials

DIN EN ISO 11135-1:2020
Sterilization of health care products – Ethylene oxide – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

DIN EN ISO 11138-1:2017
Sterilization of health care products – Biological indicators – Part 1: General requirements

DIN EN ISO 11138-2:2017
Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes

DIN EN ISO 11607-1:2017
Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems

DIN EN ISO 11607-2:2017
Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes

DIN EN ISO 11737-1:2018
Sterilization of medical - Microbiological methods – Part 1: Determination of a population of microorganisms on products

DIN EN ISO 11737-2:2010
Sterilization of medical devices – Part 2: Tests of sterility performed in the definition, validation and maintenance of the sterilization process

DIN 13273-7:2003
Catheters for medical use – Part 7: Determination of the x-ray attenuation of catheters; Requirements and testing

DIN EN ISO 13485:2016
Medical devices – Quality management systems – Requirements for regulatory purposes

DIN EN ISO 14644-1:2016
Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration

DIN EN ISO 14644-2:2016
Cleanrooms and associated controlled environments – Part 2: Specifications for monitoring to prove continued compliance with ISO 14644-1

DIN EN ISO 14971:2013
Medical devices – Application of risk management to medical devices

DIN EN ISO / IEC 17025:2018
General requirements for the competence of testing and calibration laboratories

DIN 32645:2008
Chemical analysis – Decision limit, detection limit and determination limit under repeatability conditions – Terms, methods, evaluation

DIN EN 62366:2017
Medical devices – Application of usability engineering to medical devices

ISTA 2A:2011
Guidelines for selecting and using ISTA test procedures & projects