



CERTIFICATE

EC Certificate No. 1434-MDD-034/2020

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
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

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: 2007-07-10



Application No: 333/2019
Module: H1


mgr Anna Wyroba
Vice-President



Certificate No **1434-MDD-034/2020**
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-034/2020**

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

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



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Annex no. 1 to certificate No. [1434-MDD-034/2020](#)
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ANNEX NO. 2 TO CERTIFICATE

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No **1434-MDD-034/2020**

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

Balloon Size		Order Number	Shaft length
Diameter (mm)	Length (mm)	FREEWAY™ 035	S (short) 80 cm
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



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ANNEX NO. 3 TO CERTIFICATE

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

Balloon size		Order number	Shaft length
Diameter (mm)	Length (mm)	<u>FREEWAY™ 035</u>	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



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ANNEX NO. 4 TO CERTIFICATE


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Balloon size		Order number	Shaft length
Diameter (mm)	Length (mm)	<u>FREEWAY™ 035</u>	L (long) 135 cm
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




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ANNEX NO. 5 TO CERTIFICATE

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

Balloon Size		Order Number	Shaft Length
Diameter (mm)	Length (mm)	<u>FREEWAY™ 035</u>	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

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