



CERTIFICATE

EC No 1434-MDD-133/2018
EC Design-Examination

Directive 93/42/EEC concerning medical devices

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

CARDIONOVUM GmbH

Am Bonner Bogen 2
53227 Bonn, Germany

related to the medical device
class III

XLIMUS Sirolimus Eluting Coronary Stent System

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

complies with requirements

of Annex II p. 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 11.12.2018 to 27.03.2021

The date of issue of the Certificate: 11.12.2018

The date of the first issue of the Certificate: 28.03.2013



Application No: 196/2017
Module: H1


mgr Anna Wyroba
Vice-President



Certificate No **1434-MDD-133/2018**
Issued under the Contract No **MD-01/2018**
Bears the PCBC hologram.
Warsaw, 11.12.2018



ANNEX no. 1 TO CERTIFICATE
VALID ONLY WITH CERTIFICATE
No. 1434-MDD-133/2018

The list of medical devices covered by the certificate

Stent Length (mm)	Stent Diameter (mm)							
	2.25	2.50	2.75	3.00	3.50	4.00	4.50	5.00
8	XL 2.25-8	XL 2.50-8	XL 2.75-8	XL 3.00-8	XL 3.50-8	XL 4.00-8	XL 4.50-8	XL 5.00-8
12	XL 2.25-12	XL 2.50-12	XL 2.75-12	XL 3.00-12	XL 3.50-12	XL 4.00-12	XL 4.50-12	XL 5.00-12
16	XL 2.25-16	XL 2.50-16	XL 2.75-16	XL 3.00-16	XL 3.50-16	XL 4.00-16	XL 4.50-16	XL 5.00-16
20	XL 2.25-20	XL 2.50-20	XL 2.75-20	XL 3.00-20	XL 3.50-20	XL 4.00-20	XL 4.50-20	XL 5.00-20
24	XL 2.25-24	XL 2.50-24	XL 2.75-24	XL 3.00-24	XL 3.50-24	XL 4.00-24	XL 4.50-24	XL 5.00-24
28	XL 2.25-28	XL 2.50-28	XL 2.75-28	XL 3.00-28	XL 3.50-28	XL 4.00-28	XL 4.50-28	XL 5.00-28
32	XL 2.25-32	XL 2.50-32	XL 2.75-32	XL 3.00-32	XL 3.50-32	XL 4.00-32	XL 4.50-32	XL 5.00-32
36	XL 2.25-36	XL 2.50-36	XL 2.75-36	XL 3.00-36	XL 3.50-36	XL 4.00-36	XL 4.50-36	XL 5.00-36
40	XL 2.25-40	XL 2.50-40	XL 2.75-40	XL 3.00-40	XL 3.50-40	XL 4.00-40	XL 4.50-40	XL 5.00-40



Anna Wyroba
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