EC Design Examination Certificate

Certificate No.:	Project No.:	Valid Until:
11470-2017-CE-GER-NA-PS Rev. 0.0	**PRJC-534486-2015-PRC-DEU**	**22 December 2019**

This is to certify that:

Drug Eluting Stent Delivery System

Manufactured by:

Eurocor GmbH

In den Dauen 6a
53117 Bonn
Germany

Has been assessed with respect to:

Examination of the design of the product as described in Annex II section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 25 April 2018

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Alessandra Rinna

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Replaces certificate 5326-2014-CE-GER-NA-D (NB 0434) following transfer of Notified Body functions to DNV GL Nemko Presafe AS (NB 2460)	2017-11-09
1.0	Editorial change ref. removed “(Module B1)”	2018-04-25

Products covered by this Certificate:

Type of medical device and identification no.: Sirolimus Eluting coronary stent system in Cr-Co L605 platform	**Medical Device Class:** III	**GMDN code:**
Short description of the Medical Device: E-MAGIC PLUS is a sirolimus drug eluting stent designed on the innovative Cr platform. Drug concentration is 1.3µg/mm2 and biodegradable polymers used are Poly-L-Lactide (PLA) and 50/50 Poly-dl-Lactide-co-Glycolide (DL-PLA). The stent is delivered mounted on to the PTCA balloon catheter and is sterilized by ethylene oxide. The stent falls under rule 13 and clause 7.4 in Annex I of directive 93/42/EEC. A positive opinion from a Medicine Agency has been obtained.		

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall inform Presafe of any intended change of the products detailed above and Presafe will assess the changes and decide if the certificate remains valid.

The following may render this Certificate invalid:

- Changes in the design of the products to which this Certificate refers.
- Changes in requirements of the scheme to which this Certificate refers.

Conformity declaration and marking of product

This Certificate must be accompanied with a valid EC Certificate Full Quality Assurance System.

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate