DNV·GL

EC DESIGN

Examination Certificate

Certificate No.:	Project No.:	Valid Until:
10000351742-PA-NA-IND Rev 1.0	PRJC-571497-2017-MSL-IND	29 September 2022

This is to certify that:

Sterile Coronary Stent System

Manufactured by:

Multimedics

Plot No.28, Phase -3, HPSIDC Ind. Area Baddi, Distt. Solan-173205 (HP), India

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.

Digitally signed by Guţan Ghenadie
Date: 2021.09.08 15:31:57 EEST
Reason: MoldSign Signature
Location: Moldova

Place and date:
Høvik, 25 September 2020

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Palani Damodharan

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

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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	This certificate is traceable to certificate no. 11232-2017-CE-IND-NA-PS Rev. 1.0 and Reissued after change of Project Number	14-05-2020
1.0	**Brand Addition - E-Magic Plus**	25-09-2020

Products covered by this Certificate:

Type of medical device and identification no.:	**Medical Device Class:**	**GMDN code:**
M'Sure-S, Tapper-S & **E-Magic Plus**: Sirolimus Eluting coronary stent system in Cr-Co L605 platform	III	
Short description of the Medical Device:		
M'Sure-S, Tapper-S & **E-Magic Plus** are a sirolimus drug eluting stent designed on the innovative hybrid M'Sure-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 device is available in lengths of 8, 12, 16, 20, 24, 28, 32, 36 and 40mm and expanded diameters of 2.5 to 4.0mm. 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.		

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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 updating of the quality system 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