

EC Design- Examination Certificate



**according to directive 93/42/EEC,
annex II (4)**

As a notified body of the European Union, DEKRA Certification GmbH certifies for the manufacturer

QualiMed Innovative Medizinprodukte GmbH

Boschstraße 16, 21423 Winsen, Deutschland

that the design dossier for the product(s) described in the annex complies with the requirements of the directive 93/42/EEC. This certificate is based on the result of the examination of the design dossier according to the directive 93/42/EEC annex II.4 as documented in the report mentioned in the Annex.

Product: GALAXY Rapamycin-Eluting Coronary Stent System

This certificate is valid from 2018-04-12 to 2022-07-02

Certificate registration No.: 50289-23-S3-1



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-296.10.01

DEKRA Certification GmbH Stuttgart; 2018-04-12
Notified Body ID-number: 0124

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Annex to the EC design examination certificate 50289-23-S3-1 dated 2018-04-12

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Report number: 50289-P19-02, 50289-CN17-09-CR-00

Product: GALAXY Rapamycin-Eluting Coronary Stent System

Intended use:

The product is indicated for improving coronary luminal diameter in patients. The Stent is also indicated for treatment of abrupt or threatening closure in patients with failed interventional therapy.

Technical data:

Stent Length [mm]:	10 / 14 / 18 / 24 / 28 / 34 / 38		10 / 14 / 18 / 24 / 28 / 34 / 38	
Balloon diameter [mm]:	Small: 2,0 / 2,25 / 2,5 / 2,75 / 3,0		Large: 3,25 / 3,5 / 4,0	
Balloon length [mm]:	12 / 15 / 20 / 25 / 30 / 35 / 40			
Carrier:	Poly-dl-lactid-co-glykolid (PLGA 50/50) with an average thickness of 5,0 µm; Coating amount depending on the stent-length			
Drug:	Rapamycin (Sirolimus)			
Shelf Life:	24 months			
Article code:	MR2010	MR2210	MR2510	MR2710
	MR2014	MR2214	MR2514	MR2714
	MR2018	MR2218	MR2518	MR2718
	MR2024	MR2224	MR2524	MR2724
	MR2028	MR2228	MR2528	MR2728
	MR2034	MR2234	MR2534	MR2734
	MR2038	MR2238	MR2538	MR2738
	MR3010	MR3210	MR3510	MR4010
	MR3014	MR3214	MR3514	MR4014
	MR3018	MR3218	MR3518	MR4018
	MR3024	MR3224	MR3524	MR4024
	MR3028	MR3228	MR3528	MR4028
	MR3034	MR3234	MR3534	MR4034
	MR3038	MR3238	MR3538	MR4038