EC Declaration of Conformity

We declare under our sole responsibility that the medical device

Description	Type	Catalogue Number (small version)			Catalogue Number (large version)	
Rapamycin-Eluting Coronary Stent System	**GALAXY Rapamycin-Eluting Coronary Stent System**	MR2010 MR2014 MR2018 MR2024 MR2028 MR2034 MR2038 MR2210 MR2214 MR2218 MR2224 MR2228 MR2234 MR2238	MR2510 MR2514 MR2518 MR2524 MR2528 MR2534 MR2538 MR2710 MR2714 MR2718 MR2724 MR2728 MR2734 MR2738	MR3010 MR3014 MR3018 MR3024 MR3028 MR3034 MR3038	MR3210 MR3214 MR3218 MR3224 MR3228 MR3234 MR3238 MR3510 MR3514 MR3518 MR3524 MR3528 MR3534 MR3538	MR4010 MR4014 MR4018 MR4024 MR4028 MR4034 MR4038
Explanations: MRddll dd = balloon diameter [mm/10] ll = length of the stent [mm]		Range: dd: 2.0 to 3.0 mm ll: 10 to 38 mm			Range: dd: 3.25 to 4.0 mm ll: 10 to 38 mm	

Class	Annex of the Directive	Rule
III	IX	8.2 and 13

meets all the provisions of the directive 93/42/EEC which apply to it.

Conformity assessment procedure	II.4

Certificate Number	Valid until
50289-16-06-1	26.04.2021
50289-23-S3-1	02.07.2022

Brand	Stron

EN ISO 13485:2016	Valid until
50289-14-00	26.04.2021

GMDN Code	58771

Identification Code of the Notified Body	0124	DEKRA Certification GmbH Handwerkstraße 15 D-70565 Stuttgart

Winsen, 25.03.2019

Signature:

Name (printed): Manfred Gülcher

Position: Chief Risk Officer

Manufacturer:
QualiMed
Innovative Medizinprodukte GmbH
Boschstraße 16, 21423 Winsen, Germany

This declaration of conformity is valid until: 26.04.2021