EC Declaration of Conformity

Digitally signed by Bolea Petru
Date: 2021.03.22 08:21:21 EET
Reason: MoldSign Signature
Location: Moldova

We declare under our sole responsibility that the medical device

Type	Catalogue Number (small)				Catalogue Number (large)		
POLARIS Peripheral Vascular Self Expanding Stent System		08 PS 06020	08 PS 07020	08 PS 08020	08 PS 09020	08 PS 10020	08 PS 11020
		08 PS 06040	08 PS 07040	08 PS 08040	08 PS 09040	08 PS 10040	08 PS 11040
		08 PS 06060	08 PS 07060	08 PS 08060	08 PS 09060	08 PS 10060	08 PS 11060
		08 PS 06080	08 PS 07080	08 PS 08080	08 PS 09080	08 PS 10080	08 PS 11080
		08 PS 06100	08 PS 07100	08 PS 08100	08 PS 09100	08 PS 10100	08 PS 11100
		08 PS 06120	08 PS 07120	08 PS 08120	08 PS 09120	08 PS 10120	08 PS 11120
		08 PS 06150	08 PS 07150	08 PS 08150	08 PS 09150	08 PS 10150	08 PS 11150
		12 PS 06020	12 PS 07020	12 PS 08020	12 PS 09020	12 PS 10020	12 PS 11020
		12 PS 06040	12 PS 07040	12 PS 08040	12 PS 09040	12 PS 10040	12 PS 11040
		12 PS 06060	12 PS 07060	12 PS 08060	12 PS 09060	12 PS 10060	12 PS 11060
		12 PS 06080	12 PS 07080	12 PS 08080	12 PS 09080	12 PS 10080	12 PS 11080
		12 PS 06100	12 PS 07100	12 PS 08100	12 PS 09100	12 PS 10100	12 PS 11100
		12 PS 06120	12 PS 07120	12 PS 08120	12 PS 09120	12 PS 10120	12 PS 11120
		12 PS 06150	12 PS 07150	12 PS 08150	12 PS 09150	12 PS 10150	12 PS 11150
	08 AHS 05020	08 AHS 06020	08 AHS 07020	08 AHS 08020	08 AHS 09020	08 AHS 10020	08 AHS 11020
	08 AHS 05040	08 AHS 06040	08 AHS 07040	08 AHS 08040	08 AHS 09040	08 AHS 10040	08 AHS 11040
	08 AHS 05060	08 AHS 06060	08 AHS 07060	08 AHS 08060	08 AHS 09060	08 AHS 10060	08 AHS 11060
	08 AHS 05080	08 AHS 06080	08 AHS 07080	08 AHS 08080	08 AHS 09080	08 AHS 10080	08 AHS 11080
	08 AHS 05100	08 AHS 06100	08 AHS 07100	08 AHS 08100	08 AHS 09100	08 AHS 10100	08 AHS 11100
	08 AHS 05120	08 AHS 06120	08 AHS 07120	08 AHS 08120	08 AHS 09120	08 AHS 10120	08 AHS 11120
	08 AHS 05150	08 AHS 06150	08 AHS 07150	08 AHS 08150	08 AHS 09150	08 AHS 10150	08 AHS 11150
	12 AHS 05020	12 AHS 06020	12 AHS 07020	12 AHS 08020	12 AHS 09020	12 AHS 10020	12 AHS 11020
	12 AHS 05040	12 AHS 06040	12 AHS 07040	12 AHS 08040	12 AHS 09040	12 AHS 10040	12 AHS 11040
	12 AHS 05060	12 AHS 06060	12 AHS 07060	12 AHS 08060	12 AHS 09060	12 AHS 10060	12 AHS 11060
	12 AHS 05080	12 AHS 06080	12 AHS 07080	12 AHS 08080	12 AHS 09080	12 AHS 10080	12 AHS 11080
	12 AHS 05100	12 AHS 06100	12 AHS 07100	12 AHS 08100	12 AHS 09100	12 AHS 10100	12 AHS 11100
	12 AHS 05120	12 AHS 06120	12 AHS 07120	12 AHS 08120	12 AHS 09120	12 AHS 10120	12 AHS 11120
	12 AHS 05150	12 AHS 06150	12 AHS 07150	12 AHS 08150	12 AHS 09150	12 AHS 10150	12 AHS 11150
Explanation: xx vvv ddlll xx = usable catheter length vvv= version dd = stent diameter lll = stent length	Range: xx: 80 or 120 cm PS: Legacy AHS: Advance dd: 5 to 8 mm lll: 20 to 150 mm				Range: xx: 80 or 120 cm PS: Legacy AHS: Advance dd: 9 to 11 mm lll: 20 to 150 mm		

Class	Annex of the Directive	Rule
IIb	IX	8

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

Conformity assessment procedure	II excluding section (4)

Certificate Number	Valid until
50289-16-06-1	26.04.2021

Brand	STRON

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

GMDN Code	47932

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

Winsen, 19.11.2019

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