EC Declaration of Conformity

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

We declare under our sole responsibility that the medical device

Type	Catalogue Number (small)				Catalogue Number (large)		
POLARIS-pp Peripheral Vascular Self Expanding Stent System		08 PPS 06020 08 PPS 06040 08 PPS 06060 08 PPS 06080 08 PPS 06100 08 PPS 06120 08 PPS 06150 08 PPS 06175 08 PPS 06200 12 PPS 06020 12 PPS 06040 12 PPS 06060 12 PPS 06080 12 PPS 06100 12 PPS 06120 12 PPS 06150 12 PPS 06175 12 PPS 06200	08 PPS 07020 08 PPS 07040 08 PPS 07060 08 PPS 07080 08 PPS 07100 08 PPS 07120 08 PPS 07150 08 PPS 07175 08 PPS 07200 12 PPS 07020 12 PPS 07040 12 PPS 07060 12 PPS 07080 12 PPS 07100 12 PPS 07120 12 PPS 07150 12 PPS 07175 12 PPS 07200	08 PPS 08020 08 PPS 08040 08 PPS 08060 08 PPS 08080 08 PPS 08100 08 PPS 08120 08 PPS 08150 08 PPS 08175 08 PPS 08200 12 PPS 08020 12 PPS 08040 12 PPS 08060 12 PPS 08080 12 PPS 08100 12 PPS 08120 12 PPS 08150 12 PPS 08175 12 PPS 08200	08 PPS 09020 08 PPS 09040 08 PPS 09060 08 PPS 09080 08 PPS 09100 08 PPS 09120 08 PPS 09150 12 PPS 09020 12 PPS 09040 12 PPS 09060 12 PPS 09080 12 PPS 09100 12 PPS 09120 12 PPS 09150	08 PPS 10020 08 PPS 10040 08 PPS 10060 08 PPS 10080 08 PPS 10100 08 PPS 10120 08 PPS 10150 12 PPS 10020 12 PPS 10040 12 PPS 10060 12 PPS 10080 12 PPS 10100 12 PPS 10120 12 PPS 10150	08 PPS 11020 08 PPS 11040 08 PPS 11060 08 PPS 11080 08 PPS 11100 08 PPS 11120 08 PPS 11150 12 PPS 11020 12 PPS 11040 12 PPS 11060 12 PPS 11080 12 PPS 11100 12 PPS 11120 12 PPS 11150
	08 APS 05020 08 APS 05040 08 APS 05060 08 APS 05080 08 APS 05100 08 APS 05120 08 APS 05150 08 APS 05175 08 APS 05200 12 APS 05020 12 APS 05040 12 APS 05060 12 APS 05080 12 APS 05100 12 APS 05120 12 APS 05120 12 APS 05175 12 APS 05200	08 APS 06020 08 APS 06040 08 APS 06060 08 APS 06080 08 APS 06100 08 APS 06120 08 APS 06150 08 APS 06175 08 APS 06200 12 APS 06020 12 APS 06040 12 APS 06060 12 APS 06080 12 APS 06100 12 APS 06120 12 APS 06150 12 APS 06175 12 APS 06200	08 APS 07020 08 APS 07040 08 APS 07060 08 APS 07080 08 APS 07100 08 APS 07120 0 APS 07150 08 APS 07175 08 APS 07200 12 APS 07020 12 APS 07040 12 APS 07060 12 APS 07080 12 APS 07100 12 APS 07120 12 APS 07150 12 APS 07175 12 APS 07200	08 APS 08020 08 APS 08040 08 APS 08060 08 APS 08080 08 APS 08100 08 APS 08120 08 APS 08150 08 APS 08175 08 APS 08200 12 APS 08020 12 APS 08040 12 APS 08060 12 APS 08080 12 APS 08100 12 APS 08120 12 APS 08150 12 APS 08175 12 APS 08200	08 APS 09020 08 APS 09040 08 APS 09060 08 APS 09080 08 APS 09100 08 APS 09120 08 APS 09150 12 APS 09020 12 APS 09040 12 APS 09060 12 APS 09080 12 APS 09100 12 APS 09120 12 APS 09150	08 APS 10020 08 APS 10040 08 APS 10060 08 APS 10080 08 APS 10100 08 APS 10120 08 APS 10150 12 APS 10020 12 APS 10040 12 APS 10060 12 APS 10080 12 APS 10100 12 APS 10120 12 APS 10150	08 APS 11020 08 APS 11040 08 APS 11060 08 APS 11080 08 APS 11100 08 APS 11120 08 APS 11150 12 APS 11020 12 APS 11040 12 APS 11060 12 APS 11080 12 APS 11100 12 APS 11120 12 APS 11150
Explanations: xx vvv ddlll xx = usable catheter length vvv = version dd = stent diameter [mm] lll = stent length [mm]	Range: xx: 80 or 120 cm PPS: Legacy APS: Advance dd: 5 to 8 mm lll: 20 to 200 mm				Range: xx: 80 or 120 cm PPS: Legacy APS: 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