

EC Declaration of Conformity

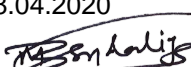
We declare under our sole responsibility that the medical device

Type	Catalogue Number (small)				Catalogue Number (large)				
POLARIS-pp Peripheral Vascular Self Expanding Stent System	08 PPS 06020	08 PPS 07020	08 PPS 08020	08 PPS 09020	08 PPS 10020	08 PPS 11020			
	08 PPS 06040	08 PPS 07040	08 PPS 08040	08 PPS 09040	08 PPS 10040	08 PPS 11040			
	08 PPS 06060	08 PPS 07060	08 PPS 08060	08 PPS 09060	08 PPS 10060	08 PPS 11060			
	08 PPS 06080	08 PPS 07080	08 PPS 08080	08 PPS 09080	08 PPS 10080	08 PPS 11080			
	08 PPS 06100	08 PPS 07100	08 PPS 08100	08 PPS 09100	08 PPS 10100	08 PPS 11100			
	08 PPS 06120	08 PPS 07120	08 PPS 08120	08 PPS 09120	08 PPS 10120	08 PPS 11120			
	08 PPS 06150	08 PPS 07150	08 PPS 08150	08 PPS 09150	08 PPS 10150	08 PPS 11150			
	08 PPS 06175	08 PPS 07175	08 PPS 08175	08 PPS 09175	08 PPS 10175	08 PPS 11175			
	08 PPS 06200	08 PPS 07200	08 PPS 08200	08 PPS 09200	08 PPS 10200	08 PPS 11200			
	12 PPS 06020	12 PPS 07020	12 PPS 08020	12 PPS 09020	12 PPS 10020	12 PPS 11020			
	12 PPS 06040	12 PPS 07040	12 PPS 08040	12 PPS 09040	12 PPS 10040	12 PPS 11040			
	12 PPS 06060	12 PPS 07060	12 PPS 08060	12 PPS 09060	12 PPS 10060	12 PPS 11060			
	12 PPS 06080	12 PPS 07080	12 PPS 08080	12 PPS 09080	12 PPS 10080	12 PPS 11080			
	12 PPS 06100	12 PPS 07100	12 PPS 08100	12 PPS 09100	12 PPS 10100	12 PPS 11100			
	12 PPS 06120	12 PPS 07120	12 PPS 08120	12 PPS 09120	12 PPS 10120	12 PPS 11120			
	12 PPS 06150	12 PPS 07150	12 PPS 08150	12 PPS 09150	12 PPS 10150	12 PPS 11150			
	12 PPS 06175	12 PPS 07175	12 PPS 08175	12 PPS 09175	12 PPS 10175	12 PPS 11175			
	12 PPS 06200	12 PPS 07200	12 PPS 08200	12 PPS 09200	12 PPS 10200	12 PPS 11200			
	08 APS 05020	08 APS 06020	08 APS 07020	08 APS 08020	08 APS 09020	08 APS 10020	08 APS 11020		
	08 APS 05040	08 APS 06040	08 APS 07040	08 APS 08040	08 APS 09040	08 APS 10040	08 APS 11040		
	08 APS 05060	08 APS 06060	08 APS 07060	08 APS 08060	08 APS 09060	08 APS 10060	08 APS 11060		
	08 APS 05080	08 APS 06080	08 APS 07080	08 APS 08080	08 APS 09080	08 APS 10080	08 APS 11080		
	08 APS 05100	08 APS 06100	08 APS 07100	08 APS 08100	08 APS 09100	08 APS 10100	08 APS 11100		
	08 APS 05120	08 APS 06120	08 APS 07120	08 APS 08120	08 APS 09120	08 APS 10120	08 APS 11120		
	08 APS 05150	08 APS 06150	08 APS 07150	08 APS 08150	08 APS 09150	08 APS 10150	08 APS 11150		
	08 APS 05175	08 APS 06175	08 APS 07175	08 APS 08175	08 APS 09175	08 APS 10175	08 APS 11175		
	08 APS 05200	08 APS 06200	08 APS 07200	08 APS 08200	08 APS 09200	08 APS 10200	08 APS 11200		
	12 APS 05020	12 APS 06020	12 APS 07020	12 APS 08020	12 APS 09020	12 APS 10020	12 APS 11020		
	12 APS 05040	12 APS 06040	12 APS 07040	12 APS 08040	12 APS 09040	12 APS 10040	12 APS 11040		
	12 APS 05060	12 APS 06060	12 APS 07060	12 APS 08060	12 APS 09060	12 APS 10060	12 APS 11060		
	12 APS 05080	12 APS 06080	12 APS 07080	12 APS 08080	12 APS 09080	12 APS 10080	12 APS 11080		
	12 APS 05100	12 APS 06100	12 APS 07100	12 APS 08100	12 APS 09100	12 APS 10100	12 APS 11100		
	12 APS 05120	12 APS 06120	12 APS 07120	12 APS 08120	12 APS 09120	12 APS 10120	12 APS 11120		
	12 APS 05120	12 APS 06150	12 APS 07150	12 APS 08150	12 APS 09150	12 APS 10150	12 APS 11150		
	12 APS 05175	12 APS 06175	12 APS 07175	12 APS 08175	12 APS 09175	12 APS 10175	12 APS 11175		
	12 APS 05200	12 APS 06200	12 APS 07200	12 APS 08200	12 APS 09200	12 APS 10200	12 APS 11200		
	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
Ib	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	
50289-16-07-1	26.05.2024	
Brand	Stron	
EN ISO 13485:2016	Valid until	
50289-14-01	18.03.2023	
GMDN Code	47932	
Identification Code of the Notified Body	0124	DEKRA Certification GmbH Handwerkstraße 15 D-70565 Stuttgart

Winsen, 08.04.2020
 Signature: 
 Name (printed): Bhavik Gondaliya
 Position: Head of Regulatory Affairs

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

This declaration of conformity is valid until: 18.03.2023