CERTIFICATE

Digitally signed by Bolea Petru
Date: 2021.09.09 17:00:38 EEST
Reason: MoldSign Signature
Location: Moldova

QualiMed®
Innovative Medizinprodukte GmbH

EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the organization

QualiMed Innovative Medizinprodukte GmbH

Scope of certification:

Design and development, manufacture and distribution of catheters, catheter systems, stents and stent systems.
Contract development and production in the field of non-active implants

Certified location:

Boschstraße 16, 21423 Winsen, Germany

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 50289-Z7-00.

Certificate registration no.:	50289-14-01	Certificate valid from:	2020-03-19
Validity of previous certificate:	2020-03-18	Certificate valid to:	2023-03-18

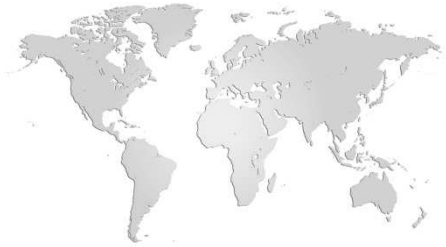
DEKRA Certification GmbH Stuttgart, Handwerkstraße 15 D-70565

DAkkS Deutsche Akkreditierungsstelle D-ZM-16029-08-00

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-03-19

EC CERTIFICATE

for the Quality Assurance System



according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

QualiMed Innovative Medizinprodukte GmbH

Boschstraße 16, 21423 Winsen, Germany

Certified location:

Boschstraße 16, 21423 Winsen, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50289-Z7-00, the decision dated 2020-03-19 and is only valid in connection with the successful performance of the annual surveillance audits.
This certificate is only valid in connection with the main certificate no. 50289-16-07.

This certificate is valid from 2020-03-19 to 2024-05-26

Registration No.: 50289-16-07-1

DEKRA Certification GmbH • D-70565 Stuttgart, Handwerkstraße 15 • DEKRA DEKRA Certification

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2020-03-19
Notified Body ID-number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Annex to the EC Certificate No. 50289-16-07-1

Valid from 2020-03-19 to 2024-05-26

Revision status of the annex: 0 dated 2020-03-19

Devices/device categories included in the certificate:

Brand: Stron

Class II a:

- PYXIS-vq PTA Balloon Catheter
- GRAVIS PTA Balloon Catheter
- DELPHINUS PTA Balloon Catheter
- LATUS PTA Balloon Catheter
- FISTULEX PTA Balloon Catheter
- FISTULEX 0.035 PTA Balloon Catheter
- PYXIS-e PTA Balloon Catheter

Class II b:

- POLARIS Peripheral Vascular Self Expanding Stent System
- POLARIS-pp Peripheral Vascular Self Expanding Stent System
- PROPOS^{S} Peripheral Balloon Expandable Stent System
- PROPOSS^{6F} Peripheral Balloon Expandable Stent System
- PROPOSX^{S} Peripheral Balloon Expandable Stent System

Class III:

- VMAX Aspiration Catheter
- GALAXY Rapamycin-Eluting Coronary Stent System
- PYXIS-c PTCA Balloon Catheter

For the placing on the market of class III devices covered by this certificate an EC design-examination certificate according to directive 93/42/EEC annex II (4) is required.

DEKRA Certification GmbH • D-70565 Stuttgart, Handwerkstraße 15 • DEKRA Certification

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-03-19
Notified Body ID-number: 0124

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

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

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

84460

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

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

Product: GALAXY Rapamycin-Eluting Coronary Stent System

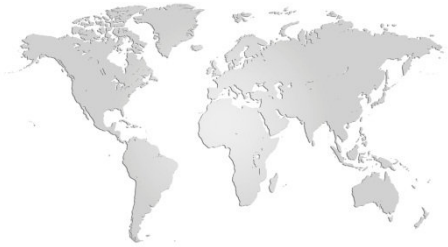
Intended use:

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

EC Design Examination Certificate



according the 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, Germany

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: **PYXIS-c PTCA Balloon Catheter**

This certificate is valid from 2019-02-20 to 2023-03-30

Registration No.: 50289-23-N5-1

DEKRA Certification GmbH • D-70565 Stuttgart, Handwerkstraße 15 • DEKRA Certification

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-02-20
Notified Body ID-number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Annex to the EC Design Examination Certificate No. 50289-23-N5-1

Revision status: 2

valid from 2021-05-21 to 2023-03-30

Report number: 50289-P14-09

Product: PYXIS-c PTCA Balloon Catheter

Intended use:

The PTCA Balloon Catheter is used to increase the luminal diameter of a coronary artery at the sites of certain types of stenotic lesions by mechanical dilatation. Thus, adequate tissue perfusion can be re-established. In addition, the procedure can be used before and after stenting of coronary arteries.
The PTCA Balloon Catheter is indicated for use in coronary vessels with vessel diameters of 1.5 mm to 5.0 mm.
The treated lesion length should be less than the nominal balloon length (10 mm - 40 mm) with reference vessel diameters from 1.5 mm to 5.0 mm.

Technical data:

Balloon diameter (mm)	1.50 / 2.00 / 2.25 / 2.50 / 2.75 / 3.00 /3.25 / 3.50 4.00 / 4.50 / 5.00
Balloon Length (mm)	10 / 11 / 12 / 15 / 16 / 20 for balloon diameters 1.50 mm 10 / 11 / 12 / 15 / 16 / 20 / 25 / 30 / 35 / 40 for balloon diameters 2.00 mm to 4.00 mm 11 /12 /16 /20 /25 /30 for balloon diameters 4.50 mm to 5.00 mm
Catalogue numbers	PC1510, PC1511, PC1512, PC1515, PC1516, PC1520
	PC2010, PC2011, PC2012, PC2015, PC2016, PC2020, PC2025, PC2030, PC2035, PC2040
	PC2210, PC2211, PC2212, PC2215, PC2216, PC2220, PC2225, PC2230, PC2235, PC2240
	PC2510, PC2511, PC2512, PC2515, PC2516, PC2520, PC2525, PC2530, PC2535, PC2540
	PC2710, PC2711, PC2712, PC2715, PC2716, PC2720, PC2725, PC2730, PC2735, PC2740
	PC3010, PC3011, PC3012, PC3015, PC3016, PC3020, PC3025, PC3030, PC3035, PC3040
	PC3210, PC3211, PC3212, PC3215, PC3216, PC3220, PC3225, PC3230, PC3235, PC3240
	PC3510, PC3511, PC3512, PC3515, PC3516, PC3520, PC3525, PC3530, PC3535, PC3540
	PC4010, PC4011, PC4012, PC4015, PC4016, PC4020, PC4025, PC4030, PC4035, PC4040
	PC4511, PC4512, PC4516, PC4520, PC4525, PC4530
	PC5011, PC5012, PC5016, PC5020, PC5025, PC5030

DEKRA Certification GmbH Stuttgart Handwerkstraße 15 D-70565

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2021-05-21
Notified Body ID-number: 0124

CERTIFICATE

EC Certificate No. 1434-MDD-068/2020
Full Quality Assurance System

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

QualiMed Innovative Medizinprodukte GmbH

Boschstrasse 16, 21423 Winsen
Germany

for the design, manufacture and final inspection of

medical devices, class III

GALAXY
Sirolimus-Eluting Coronary Stent-System

complies with requirements
of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 2020-02-24 to 2024-05-27

The date of issue of the Certificate: 2020-02-24

CE 1434

Application No: 249/2018
Module H

Anna Wyroba
Vice-President

Polish Centre for Testing and Certification 23A Kłobucka Street, 02-699 Warsaw Poland, phone +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

Certificate No. **1434-MDD-068/2020**
Issued under the Contract No. **MD-75/2018**
Bears the PCBC hologram
Warsaw, 24/02/2020

CERTIFICATE

EC Certificate No. 1434-MDD-067/2020
EC Design-examination

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the documentation submitted by:

QualiMed Innovative Medizinprodukte GmbH

Boschstrasse 16, 21423 Winsen
Germany

related to the medical device, class III

GALAXY
Sirolimus-Eluting Coronary Stent-System
The list of medical devices covered by this certificate is given in the Annex to the Certificate

was examined in accordance with Annex II (Section 4) to Directive 93/42/EEC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 2020-02-24 to 2024-05-27

The date of issue of the Certificate: 2020-02-24

CE 1434

Application No: 249/2018
Module H

Anna Wyroba
Vice-President

Certificate No. **1434-MDD-067/2020**
Issued under the Contract No. **MD-75/2018**
Bears the PCBC hologram
Warsaw, 24/02/2020

ANNEX TO CERTIFICATE
VALID ONLY WITH CERTIFICATE
No 1434-MDD-067/2020

Technical Data – GALAXY Sirolimus-Eluting Coronary Stent System
Brand: STRON

PTCA Catheter	
Balloon diameter (mm)	Small: 2,0 / 2,25 / 2,5 / 2,75 / 3,0 Large: 3,25 / 3,5 / 4,0
Balloon Length	12 / 15 / 20 / 25 / 30 / 35 / 40
Stent	
Stent length (mm)	Small: 10 / 14 / 18 / 24 / 28 / 34 / 38 Large: 10 / 14 / 18 / 24 / 28 / 34 / 38
Stent Material	Stainless Steel with carbon ion implantation
Drug	Sirolimus, 2.0 µg/mm^2
Carrier:	Poly-DL- lactide-co-glycolide (PLGA 50/50)
Sterilization method	ETO gas
Shelf Life:	24 months
Catalogue numbers (Small Version)	MRB2010, MRB2014, MRB2018, MRB2024, MRB2028, MRB2034, MRB2038 MRB2210, MRB2214, MRB2218, MRB2224, MRB2228, MRB2234, MRB2238 MRB2510, MRB2514, MRB2518, MRB2524, MRB2528, MRB2534, MRB2538 MRB2710, MRB2714, MRB2718, MRB2724, MRB2728, MRB2734, MRB2738, MRB3010, MRB3014, MRB3018, MRB3024, MRB3028, MRB3034, MRB3038
Catalogue numbers (Large Version)	MRB3210, MRB3214, MRB3218, MRB3224, MRB3228, MRB3234, MRB3238 MRB3510, MRB3514, MRB3518, MRB3524, MRB3528, MRB3534, MRB3538 MRB4010, MRB4014, MRB4018, MRB4024, MRB4028, MRB4034, MRB4038

CE 1434

Anna Wyroba
Vice-President

Annex to certificate No. **1434-MDD-067/2020**
Issued under the Contract No. **MD-75/2019**
Bears the PCBC hologram.
Warsaw, 24.02.2020

EC Declaration of Conformity

We declare under our sole responsibility that the medical device

Description	Type	Catalogue Number (small version)			Catalogue Number (large version)	
Sirolimus-Eluting Coronary Stent System	**GALAXY Sirolimus-Eluting Coronary Stent System**	MRB2010 MRB2014 MRB2018 MRB2024 MRB2028 MRB2034 MRB2038 MRB2210 MRB2214 MRB2218 MRB2224 MRB2228 MRB2234 MRB2238	MRB2510 MRB2514 MRB2518 MRB2524 MRB2528 MRB2534 MRB2538 MRB2710 MRB2714 MRB2718 MRB2724 MRB2728 MRB2734 MRB2738	MRB3010 MRB3014 MRB3018 MRB3024 MRB3028 MRB3034 MRB3038	MRB3210 MRB3214 MRB3218 MRB3224 MRB3228 MRB3234 MRB3238 MRB3510 MRB3514 MRB3518 MRB3524 MRB3528 MRB3534 MRB3538	MRB4010 MRB4014 MRB4018 MRB4024 MRB4028 MRB4034 MRB4038
Explanations: dd = balloon diameter [mm] 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**	- **Rule 8.2** - **Rule 13**

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

Conformity assessment procedure	II.4

Certificate Number	Valid until
1434-MDD-067/2020	27.05.2024
1434-MDD-068/2020	27.05.2024

Brand	Stron

EN ISO 13485:2016	Valid until
M - 72/1/2019	01.08.2022

GMDN Code	58771

Identification Code of the Notified Body	1434	**PCBC S.A.** Ul Klobucka 23A 02-699 Warszawa Poland

Winsen, 03.03.2020

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: 01.08.2022

EC Declaration of Conformity

We declare under our sole responsibility that the medical device

Description	Type	Catalogue Number		
PTA Balloon Catheter	**GRAVIS PTA Balloon Catheter**	**GRAVIS PTA Balloon Catheter catalogue number configuration : ccPVQdddlllghx**		
		Digit	**Description**	**Range**
		1 to 2	cc = usable catheter length (UCL)	04 (45 cm), 08 (80 cm), 12 (120 cm), 15 (150 cm)
		3 to 5	PVQ = product ID	PVQ
		6 to 8	ddd = balloon diameter	3.0 to 12.0 mm
		9 to 11	lll = balloon length	10 to 280 mm
		12	g = guidewire	A = 0.035"
		13	h = coating	P = coated S = uncoated
		14	x = catheter design	O = over the wire

Class	Annex of the Directive	Rule
IIa	**IX**	**7**

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	17184

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

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 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
50289-16-07-1	**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

EC Declaration of Conformity

We declare under our sole responsibility that the medical device

Description	Type	Catalogue Number		
Peripheral Balloon Expandable Stent System	**PROPOS *S 6F* Peripheral Balloon Expandable Stent System**	08 QBX 050176F 08 QBX 050266F 08 QBX 050366F 08 QBX 050576F 08 QBX 060176F 08 QBX 060266F 08 QBX 060366F 08 QBX 060576F 08 QBX 070176F 08 QBX 070266F 08 QBX 070366F 08 QBX 070576F 08 QBX 080176F 08 QBX 080266F 08 QBX 080366F 08 QBX 080576F 08 QBX 090176F 08 QBX 090266F 08 QBX 090366F 08 QBX 090576F 08 QBX 100176F 08 QBX 100266F 08 QBX 100366F 08 QBX 100576F	12 QBX 050176F 12 QBX 050266F 12 QBX 050366F 12 QBX 050576F 12 QBX 060176F 12 QBX 060266F 12 QBX 060366F 12 QBX 060576F 12 QBX 070176F 12 QBX 070266F 12 QBX 070366F 12 QBX 070576F 12 QBX 080176F 12 QBX 080266F 12 QBX 080366F 12 QBX 080576F 12 QBX 090176F 12 QBX 090266F 12 QBX 090366F 12 QBX 090576F 12 QBX 100176F 12 QBX 100266F 12 QBX 100366F 12 QBX 100576F	15 QBX 050176F 15 QBX 050266F 15 QBX 050366F 15 QBX 050576F 15 QBX 060176F 15 QBX 060266F 15 QBX 060366F 15 QBX 060576F 15 QBX 070176F 15 QBX 070266F 15 QBX 070366F 15 QBX 070576F 15 QBX 080176F 15 QBX 080266F 15 QBX 080366F 15 QBX 080576F 15 QBX 090176F 15 QBX 090266F 15 QBX 090366F 15 QBX 090576F 15 QBX 100176F 15 QBX 100266F 15 QBX 100366F 15 QBX 100576F
Explanations: xx QBX dddllcc xx = usable catheter length ddd = stent diameter [mm] ll = stent length [mm] cc = introducer compatibility		Range: xx: 80, 120, 150 cm ddd: 5.0 to 10.0 mm ll: 17 to 57 mm cc: 6F		

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
50289-16-07-1	**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

EC Declaration of Conformity

We declare under our sole responsibility that the medical device

Description	Type	Catalogue Number				
PTCA Balloon Catheter	**PYXIS-c Balloon Catheter**	PC1510 PC1511 PC1512 PC1515 PC1516 PC1520 PC2010 PC2011 PC2012 PC2015 PC2016 PC2020 PC2025 PC2030 PC2035 PC2040	PC2210 PC2211 PC2212 PC2215 PC2216 PC2220 PC2225 PC2230 PC2235 PC2240 PC2510 PC2511 PC2512 PC2515 PC2516 PC2520 PC2525 PC2530 PC2535 PC2540	PC2710 PC2711 PC2712 PC2715 PC2716 PC2720 PC2725 PC2730 PC2735 PC2740 PC3010 PC3011 PC3012 PC3015 PC3016 PC3020 PC3025 PC3030 PC3035 PC3040	PC3210 PC3211 PC3212 PC3215 PC3216 PC3220 PC3225 PC3230 PC3235 PC3240 PC3510 PC3511 PC3512 PC3515 PC3516 PC3520 PC3525 PC3530 PC3535 PC3540	PC4010 PC4011 PC4012 PC4015 PC4016 PC4020 PC4025 PC4030 PC4035 PC4040 PC4511 PC4512 PC4516 PC4520 PC4525 PC4530 PC5011 PC5012 PC5016 PC5020 PC5025 PC5030
Explanations: PCddll dd = balloon diameter ll = stent length [mm]		Range: dd: 1.5 to 5.0 mm ll: 10 to 40 mm				

Class	Annex of the Directive	Rule
III	**IX**	**7.1**

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

Conformity assessment procedure	II.4

Certificate Number	Valid until
50289-16-07-1	**26.05.2024**
50289-23-N5-1	**30.03.2023**

EN ISO 13485:2016	Valid until
50289-14-01	**18.03.2023**

GMDN Code	47732

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

Winsen, 18.08.2020

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

EC Declaration of Conformity

We declare under our sole responsibility that the medical device

Description	Type	Catalogue Number	
Aspiration Catheter	**VMAX Aspiration Catheter**	VX6HI3 VX6HI3B VX6HI5 VX6HI5B VX6HO5 VX6HO5B	VX7HI3 VX7HI3B VX7HI5 VX7HI5B
Explanations: **6** = 6.0F; **7** = 7.0F Catheter Size **H** = Hydrophilic Coating; **I3, I5** and **O5** = Design **B** = Packaging (Aspiration Catheter only)			

Class	Annex of the Directive	Rule
III	**IX**	**7.1**

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

Conformity assessment procedure	II.4

Certificate Number	Valid until
50289-16-07-1	**26.05.2024**
50289-23-Q3-1	**02.04.2023**

Brand	Stron

EN ISO 13485:2016	Valid until
50289-14-01	**18.03.2023**

GMDN Code	58173

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