

# EC Declaration of Conformity

We declare under our sole responsibility that the medical device

Description	Type	Catalogue Number		
PTA Balloon Catheter	PERSEUS-q PTA Balloon Catheter	PERSEUS-vq PTA Balloon Catheter catalogue number configuration: ccPVQdddlllghxzz		
		Digit	Description	Range
		1 to 2	cc = usable catheter length (UCL)	04 (45 cm), 08 (80 cm), 12 (120 cm), 13 (135 cm), 15 (150 cm), 16(160 cm)
		3 to 5	PVQ = product ID	PVQ
		6 to 8	ddd = balloon diameter	1.25 to 12.0 mm
		9 to 11	lll = balloon length	10 to 280 mm
		12	g = Guidewire	A = 0.035" B = 0.018" C = 0.014"
		13	h = coating	P = coated S = uncoated
		14	x = catheter design	O = over the wire R = rapid exchange D = dialysis fistulae catheter H = high pressure
		15	zz = Version O	5F = (long cones)

Class	Annex of the Directive	Rule
Ila	IX	7

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

Conformity assessment procedure	II excluding section (4)
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Certificate Number	Valid until
50289-16-07-3	26.05.2024

Brand	IK
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EN ISO 13485:2016	Valid until
50289-14-02	09.03.2025

GMDN Code	17184
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Identification Code of the Notified Body	0124	DEKRA Certification GmbH Handwerkstraße 15 D-70565 Stuttgart
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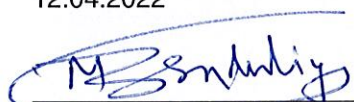
Winsen,

12.04.2022

Signature:

Name (printed):

Position:

  
Bhavik Gondaliya  
Head of Regulatory Affairs

Manufacturer:

QualiMed

Innovative Medizinprodukte GmbH  
Boschstraße 16, 21423 Winsen, Germany

This declaration of conformity is valid until: 26.05.2024