EC Design Examination Certificate

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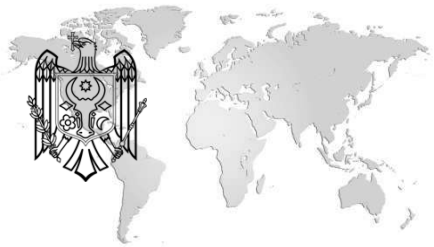

according the directive 93/42/EEC, Annex II (4)

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: **VMAX Aspiration Catheter**

This certificate is valid from 2018-11-19 to 2023-04-02

Registration No.: 50289-23-Q3-1

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

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

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2018-11-19
Notified Body ID-number: 0124

Annex to the EC Design Examination Certificate No. 50289-23-Q3-1

Revision status: 1

valid from 2019-11-11 to 2023-04-02

Report number: 50289-P17-07

Product: VMAX Aspiration Catheter

Intended use:

The Aspiration Catheter is used to contain and aspirate embolic material (thrombus/debris) by percutaneous suction.
The Aspiration catheter is indicated for use in the central and peripheral circulatory system in patients with thrombotic occlusion in coronary and peripheral arterial diseases.

Technical data:

Usable catheter length (mm)	1350 - 1410	
Length of the aspiration opening (mm)	4.8	
guide wire lumen location	Inside or outside of catheter	
Compatible Guiding catheter	6F, 7F	
Coating	hydrophilic (H)	
Article codes The Aspiration Catheter is delivered as aspiration catheter only (B) or as set with necessary components.	VX6HI3 VX6HI3B VX6HI5 VX6HI5B VX6HO5 VX6HO5B	VX7HI3 VX7HI5 VX7HI3B VX7HI5B

Ruth Delbeck-Bayer
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