EC Declaration of Conformity

Digitally signed by Bolea Petru
Date: 2020.07.07 08:54:46 EEST
Reason: MoldSign Signature
Location: Moldova

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
50289-16-06-1	26.04.2021
50289-23-Q3-1	02.04.2023

Brand	Stron

EN ISO 13485:2016	Valid until
50289-14-00	26.04.2021

GMDN Code	58173

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

Winsen, 25.03.2019

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