EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

MicroVention Europe SARL

30 bis, rue du Vieil Abreuvoir
78100 Saint-Germain-en-Laye
France

that the design of the following device(s)

CASPER™ Carotid Stent System / Roadsaver™ Carotid Stent System
CASPER™ X Carotid Stent System / Roadsaver™ X Carotid Stent System

is conform to the Essential Requirements of Annex I of the Council Directive 93/42/EEC concerning medical devices.
This EC Design Examination Certificate is only valid in connection with the valid DQS Medizinprodukte GmbH Certificate No. 487703 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination: ST18-0003 Casper Roadsaver STED.pdf dated 2019-08-23
ST18-0003 Rev. C_CASPER Roadsaver STED_19MAR2021.docx dated 2021-03-18

Further basis for the examination is referenced in the examination report and relating documents mentioned below.

Examination report: 411_18e_Report_TFR_CASPER_Roadsaver.docx dated 2020-04-21
411_18e_Report_TFR_CASPER_X_Roadsaver_X_V2.docx dated 2021-04-08

The results of the examination are contained in the above mentioned report and the relating documents mentioned within.

Certificate registration no.	514729 MRA
Certificate unique ID	170775599
Effective date	2021-04-08
Expiry date	2024-05-26
Frankfurt am Main	2021-04-08

Sigrid Uhlemann
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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.