



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 Abreuvor
78100 Saint-Germain-en-Laye
France

that the design of the following device(s)

Low-Profile Visualized Intraluminal Support Device in the variants as listed in Annex

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: LVIS STED_Final Version_Amended July 10 2019.docx
dated 2019-07-10
ST19-005 Revision B_LVIS STED_Mar2020_Clean Copy.docx
dated 2020-03-16

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

Examination report: 411_18e_Report_TFR_LVIS_LVIS Jr. docx dated 2019-07-22
411133_Report_TFR_LVIS_LVIS Jr_V2.docx dated 2020-05-05

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

Certificate registration no. 490690 MRA

Certificate unique ID 170769614

Effective date 2020-05-05

Expiry date 2024-05-26

Frankfurt am Main 2020-05-05

DQS Medizinprodukte GmbH

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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.



Annex to certificate

Certificate registration No.: 490690 MRA

Certificate unique ID: 170769614

Effective date: 2020-05-02

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Low-Profile Visualized Intraluminal Support Device

LVIS™ Intraluminal Support Device
LVIS™ Jr. Intraluminal Support Device
LVIS™ EVO™ Intraluminal Support Device
LVIS™ X™ Intraluminal Support Device
LVIS™ Jr. X™ Intraluminal Support Device
LVIS™ EVO™ X™ Intraluminal Support Device