EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

MicroVention Europe

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

that the design of the following device(s)

PHIL™ Liquid Embolic 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. 517356 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination:
Amendment Syringe Cap dated 2016-12-13
Desgin Dossier LifePearl Class III dated 2017-07-17
FD16-0172C STED PHIL Dossier.pdf dated 2018-09-07
FD16-0172D STED PHIL Dossier dated 2019-01-04

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

Examination report:
Report_PHIL_Change Syringe Cap V2 dated 2017-02-03
Report_TFR_LifePearl_(III) V1 dated 2017-11-11
Report_PHIL_Change_LV & Production_Site_V5.doc dated 2018-11-06
Report_PHIL_Change_Shelf Life 2 Years_V6.doc dated 2019-03-08

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

Certificate registration no.	517356 MRA
Certificate unique ID	170736556
Effective date	2019-03-08
Expiry date	2022-03-01
Frankfurt am Main	2019-03-08

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

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

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