EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

Sequent Medical Inc.

11A Columbia
Aliso Viejo, CA, 92656
United States of America

that the design of the following device(s)

VIA™ Microcatheter

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. 456350 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination: TF037 A – VIA Microcatheters 2017 dated 2017-07-27
TF037 C_VIA dated 2018-10-17

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

Examination report: 411_18e_Report_TFR_VIA_Sequent_V1.docx dated 2017-10-21
411_18e_Report_TFR_VIA_Sequent_V2 dated 2018-11-30

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

Certificate registration no.	507073 MRA
Certificate unique ID	170721341
Effective date	2018-11-30
Expiry date	2022-11-06
Frankfurt am Main	2018-11-30

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.