EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

KARL STORZ SE & Co. KG

Dr.-Karl-Storz-Straße 34
78532 Tuttlingen
Germany

that the design of the following device(s)

Mega Fix® in the following variants:
Mega Fix® B
Mega Fix® C
Mega Fix® CP
Mega Fix® P

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. 528525 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination: Megafix dated 2019-10-30

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

Examination report: 528525_204199_Report_TFR_MegaFix_2.docx dated 2019-12-08

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

Digitally signed by Gherman Irina
Date: 2022.02.24 14:04:44 EET
Reason: MoldSign Signature
Location: Moldova

Certificate registration no.	538785 MRA
Certificate unique ID	170759911
Effective date	2019-12-11
Expiry date	2024-05-26
Frankfurt am Main	2019-12-11

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.