EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

Laboratoires FILORGA S.A.S.

2-4 rue de Lisbonne
75008 Paris
France

that the design of the following device(s)

X-HA Volume

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. 339178 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination: DTC05.12 XHAVolume dated 2015-01-07

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

Examination report: 15_Bericht_EGA_Filorga_MHA18&XHAVolume dated 2015-03-28

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

Certificate registration no.	478711 MRA
Certificate unique ID	170618590
Effective date	2015-03-28
Expiry date	2020-03-27
Frankfurt am Main	2015-03-28

DQS Medizinprodukte GmbH

Frank Graichen
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Head of Certification Body

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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.

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