EC Certificate Full Quality Assurance System: Certificate CH12/0863



The management system of

Veldana Medical SA

Avenue Riond-Bosson 14 CH - 1110 Morges

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Cavaterm™ Plus catheters and Cavaterm™ Central Units (CU3, CU31) for the treatment of dysfunctional uterine bleeding.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 29 August 2017 until 13 May 2021 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 1 May 2019

Issue 7. Certified since 4 July 1996

Certification is based on reports numbered CH/GE 3301271

Authorised by



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Page 1 of 1





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