EC CERTIFICATE

Certificate No 1298/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

ESACROM SRL

40026 IMOLA (BO) - VIA ZAMBRINI 6/A (ITA) - Italy

manages in the factory of:

40026 IMOLA (BO) - VIA ZAMBRINI 6/A (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

Equipment for bone ultrasound surgery, debridement and for soft tissue ultrasound surgery

Type ref. SURGYSONIC WOUND.
Trade mark ESACROM

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:
10AK00009; 10AK00134; DM14A0350484-01; DM15E0484668-01; DM19-0044789-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date:	2010-02-09
Updated:	2020-01-29
Substitution Date:	2015-07-13
Expiry Date:	2024-05-26

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IMQ