



EC CERTIFICATE

Certificate No 874/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:

Micromotors for dental and surgical use

Devices for physiotherapy and medical ultrasound therapy

Multifunctional devices - micromotors, equipment for bone ultrasound surgery, for debridement and for soft tissue ultrasound surgery

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

series and type refs in the Annex

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:

10AF00201; 10AG00077; 10AH00166; 10AH00167; 10AI00148; 10EK00062; 10AO00139; DM14A0350484-01; DM15E0484668-01; DM15E0534814-01; DM16A0660614-01; DM16-0001887; DM19-0034305-01; DM19-0044789-01; DM20-0050104-01; DM20-0058201-01.

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: 2005-10-18
 Updated: 2020-12-01
 Substitution Date: 2020-04-15
 Expiry Date: 2024-05-26



 Giorgi Fulvio
IMQ DocuSign



EC CERTIFICATE

Certificate No 874/MDD

Annex

Micromotors for dental and surgical use

Type ref. BMS IMPLANT II; BMS IMPLANT II G; BMS IMPLANT II DUO; BMS IMPLANT II DUO G; BMS IMPLANT II E.

Trade mark ESACROM

Type ref. RIGENERA OR PRO.

Trade mark HBW

Devices for physiotherapy and medical ultrasound therapy

Type ref. LF ESASOUND.

Trade mark ESACROM

Multifunctional devices - micromotors, equipment for bone ultrasound surgery, for debridement and for soft tissue ultrasound surgery

Type ref. SURGYSONIC MOTO; SURGYSONIC MOTO G.

Trade mark ESACROM

Type ref. RIGENERA SONIC

Trade mark HBW

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

Type ref. SURGYSONIC II; SURGYSONIC II G; SURGYSONIC II DUO; SURGYSONIC II DUO G.

Trade mark ESACROM

Type ref. HYPERS.

Trade mark ESACROM

Date: 2005-10-18
 Updated: 2020-12-01
 Substitution Date: 2020-04-15
 Expiry Date: 2024-05-26


 Giorgi Fulvio
 IMQ DocuSign