



EC CERTIFICATE

Certificate No 1905/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:

BIOSAF IN S.R.L.

20060 TREZZANO ROSA (MI) - VIA CAGLIARI 32/44 (ITA) - Italy

manages in the factory of:

60131 ANCONA (AN) - VIA AMATO TIRABOSCHI 36/G (ITA) - Italy

20060 TREZZANO ROSA (MI) - VIA CAGLIARI 32/44 (ITA) - Italy

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

Equipment for bone ultrasound surgery

Micromotors for implantology

Inserts for equipment for bone ultrasound surgery

Sterile dental implants

Prosthetic components

Surgical drills and rotary instruments

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:

DM16-0003035; DM18-0023444-01; DM18-0032794-01.

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: 2016-09-30
 Updated: 2020-04-03
 Substitution Date: 2018-03-20
 Expiry Date: 2021-09-29



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Annex

Equipment for bone ultrasound surgery

Type ref. EASY SURGERY
Trade mark BioSAF IN

Micromotors for implantology

Type ref. EASY PHYSIO
Trade mark BioSAF IN

Inserts for equipment for bone ultrasound surgery

Type ref. PT 501; PT 504; PT 508; PT 509; PT 510; PT 511; PT 512; PT 513; PT 516; PT 518; PT 519; PT 505; PT 506;
PT 507; PT 502; PT 514; PT 515; PTW001; PTW002; PTW003; PTW004; PTW005; PTW006; PT 527; PT 528; PT 529;
PT 530; PT 520; PT 521; PT 522; PT 523; PT 524; PT 525; PT 526.
Trade mark BioSAF IN

Sterile dental implants

Type ref. As to document "Codifica_Impianti_Dentali_ED01_rev.00 dated 31/05/2019"; valid only if provided with IMQ stamp

Prosthetic components

Type ref. As to document "Codifica_Componenti protesiche_ED01_rev.00 dated 31/05/2019"; valid only if provided with IMQ stamp

Surgical drills and rotary instruments

Type ref. As to document "Codifica_Strumentario_ED01_rev.00 dated 31/05/2019"; valid only if provided with IMQ stamp

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