



EC CERTIFICATE

Certificate No 1668/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:

HMC PREMEDICAL SPA

41037 MIRANDOLA (MO) - VIA BOSCO 1/3 (ITA) - Italy

manages in the factory of:

41037 MIRANDOLA (MO) - VIA BOSCO 1/3 (ITA) - Italy

41036 MEDOLLA (MO) - VIA GALILEI 6 (ITA) - Italy

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

Custom procedure Trays

Lines for dialysis and accessories

Enteral and parenteral nutrition systems and accessories

Photo immuno therapy kit

Transfusion sets and accessories

Infusion sets and accessories – infusion sets for antiproliferative drugs

Thoracic drainage and post operative systems

Washing systems

Nasogastric tubes

Surfactant Kit

Rectal tubes and straws

Set for production, dispensation, infusion and accessories

Not active suction systems

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.

Date: 2014-04-22
 Updated: 2021-05-07
 Substitution Date: 2021-03-19
 Expiry Date: 2024-04-18



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