

EC CERTIFICATE

Certificate No 098/MDD

Production Quality Assurance System Approval Certificate

On the basis of our assessment carried out according to Annex V of the Directive 93/42/EEC and its revised version, we hereby certify that:

NORDITALIA ELETTROMEDICALI SRL

25015 SAN MARTINO DELLA BATTAGLIA (BS) - VIA COLLI STORICI 215 (ITA) - Italy

manages in the factories of:

25010 SAN MARTINO DELLA BATTAGLIA (BS) - VIA COLLI STORICI 215 (ITA) - Italy

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

Aerosoltherapy equipment and related accessories

Ultrasonic aerosoltherapy equipment and related accessories

Aspirators and related accessories

Electronic thermometer

Infrared medical thermometers

Non invasive Sphygmomanometer

series and type refs in the Annex


with the relevant essential requirements of the aforementioned directive (as far as all the manufacturing stage is concerned).

Reference to IMQ files Nos: 10A9800184; 10A9800185; 10A9800186; 10A9800187; 10A9800188; 10A9800198; 10A99A0024 ; 10A99A0025; 10A99A0026; 10AA00099; 10AA00100; 10AA00259; 10AA00260; 10AA00261; 10AB00070; 10AB00071; 10AB00197; 10AC00030; 10AD00111; 10AD00258; 10AE00058; 10AE00059; 10AE00196; 10AF00120; 10AF00174; 10AG00003; 10AG00118; 10AG00169; 10AH00001; 10AH00177; 10AI00051; 10AI00159; 10AJ00002; 10AK00077; 10EK00032; COMEDCONMDDM100012251-01; COMEDCONMDDM100014457-01; COMEDCONMDDM100013501-01.

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: 2000-01-31
Updated: 2011-04-06
Substitution Date: 2011-01-24


IMQ

This Approval Certificate is subjected to the provisions laid down in the "Rules for managing the EC Certification of Medical Devices on the basis of the Directive 93/42/EEC".
In any case, it does not remain valid after 2016-04-05 (article 11, clause 11 of the Directive).

This is a translation of the Italian text, which prevails in case of doubts

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Annex

Aerosoltherapy equipment and related accessories

Type ref. as to document:

"Elenco prodotti sotto marcatura CE", valid only if provided with IMQ stamp.

Ultrasonic aerosoltherapy equipment and related accessories

Type ref. as to document:

"Elenco prodotti sotto marcatura CE", valid only if provided with IMQ stamp.

Aspirators and related accessories

Type ref. as to document:

"Elenco prodotti sotto marcatura CE", valid only if provided with IMQ stamp.

Electronic thermometer

Type ref. as to document:

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Infrared medical thermometers

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