

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 GROUP SRL

25015 DESENZANO DEL GARDA (BS) - VIA DEI COLLI STORICI 215 (ITA) - Italy

manages in the factories of:

25015 DESENZANO DEL GARDA (BS) - VIA DEI COLLI STORICI 215 (ITA) - Italy

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

Aerosoltherapy equipment and related accessories

Ultrasonic aerosoltherapy equipment and related accessories

Electronic thermometer

Non invasive Sphygmomanometer

series and type refs in the Annex

with relevant essential requirements of the aforementioned directive (as far as all the manufacturing stage is concerned) and it is subject to surveillance as specified in section 4 of Annex V. For class IIb devices, this certificate is valid only with the relevant certificate of Annex III.

Reference to IMQ files Nos:

DM15A0528727-01; DM16A0584871-01; DM16-0000075; DM17-0009902-01;
DM17-0012765.

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: 2017-06-08
Substitution Date: 2017-04-21
Expiring Date: 2021-04-05



IMQ



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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".

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", Rev. 34 dated 24/05/2017; valid only if provided with IMQ stamp.

Ultrasonic aerosoltherapy equipment and related accessories

Type ref. as to document: "Elenco prodotti sotto marcatura CE", Rev. 34 dated 24/05/2017; valid only if provided with IMQ stamp.


Electronic thermometer

Type ref. as to document: "Elenco prodotti sotto marcatura CE", Rev. 34 dated 24/05/2017; valid only if provided with IMQ stamp.

Non invasive Sphygmomanometer

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