

EC CERTIFICATE

Certificate No 155/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:

DELTA P SRL

20088 ROSATE (MI) - VIA THANSAU 4 (ITA) - Italy

manages in the factory of:

20088 ROSATE (MI) - VIA THANSAU 4 (ITA) - Italy

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

Medical gases pressure reducers

Terminal units for compressed medical gases and vacuum

In-line medical gases pressure regulators

Terminal units for anaesthetic gas scavenging systems

Pipelines for compressed medical gases and vacuum

Medical humidifiers for oxygentherapy

High pressure flexible connections for use with medical gases

Anaesthetic gas scavenging disposal systems

Medical gas high pressure ramps

Vacuum regulators for anaesthetic gas scavenging systems (AGSS)

Vacuum regulators for endocavitary suction

Collection and safety containers

Medical gases flowmeters

First stage decompression units for medical gases

Shut-off area valves

Oxygen concentrators

Supply systems with compressor for medical air

series and type refs in the Annex

 Date:
 1999-02-19

 Updated:
 2018-07-23

 Substitution Date:
 2017-11-23

 Expiry Date:
 2022-11-22

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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:

DM15A0402959-01; DM15A0504037-01; DM17-0016500-01; DM17-0015495; DM-18-0028318-01.

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.

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Annex

Medical gases pressure reducers

Terminal units for compressed medical gases and vacuum

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Type ref. as per DELTA P S.r.l. list DM_DP Ver. 12 - 2018.06.20; valid only if provided with IMQ stamp.

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