

Notified Body n° 0426



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ITALCERT

certifies that

Full Quality Assurance System
applied for the design, manufacture and final inspection
of “Medical Devices” - MD -

by the manufacturer

MD S.r.l.

Via Guido Rossa, 22/c - 30037 SCORZÈ (VE) - ITALY

in the headquarters located in

Via Guido Rossa, 22/c
30037 SCORZÈ (VE) - ITALY

complies with the requirements stated in

Directive 93/42/EEC - Annex II (excluding point 4)

and authorizes the same manufacturer to mark

CE 0426

in compliance with the criteria defined in Annex XII of the Directive 93/42/EEC
the MD reported in Annex 1 of this Certificate

dr. ing. Roberto Cusolito


MANAGING DIRECTOR

First Issue date
2006-05-24

Renewal date
2019-05-24

Expire date
2024-05-23

This certificate must be published only in integral form and accompanied by its Annex 1.
This certificate is the English translation of the certificate n°062-03-00-DM issued by ITALCERT Srl in Italian language.
In case of discrepancy you must refer to the original certificate issued in Italian language.

Annex 1 to the Certificate n° 062-03-00-DM

- page 1 of 2 -

Active medical device intended to administer and/or remove medicines, body liquids or other substances to or from the body

- Terminal units for medical gas and vacuum pipeline systems (class IIb)
 - PF-01xx-yyyy Base blocks for terminal units for medical gas pipeline systems
 - PF-02xx-yyyy Outlets for terminal units for medical gas pipeline systems
 - PF-06xx-yyyy Probes for terminal units for medical gas pipeline systems
 - PF-36xx-yyyy Doublers for terminal units for medical gas pipeline systems
 - KT-02xx-yyyy Maintenance kits for terminal units
 - PF-34xx-yyyy Pre-installed terminal units boxes
 - PF-66xx-yyyy Hose assemblies
 - KT-01xx-yyyy Maintenance kits for base blocks

- Second stage pressure regulators for medical gas pipeline systems (class IIb)
 - PF-05xx-yyyy / PF-37xx-yyyy Line pressure regulators for medical gas pipeline systems
 - KT-05xx-yyyy / KT-37xx-yyyy Maintenance kits for line pressure regulators
 - PF-55xx-yyyy High flow line pressure regulators
 - KT-55xx-yyyy Maintenance kits for high flow line pressure regulators
 - PF-44xx-yyyy Pre-assembled cabinets for second stage pressure regulation / line pressure stabilization and regulation cabinets

- Terminal units for type 1 AGSS (Anaesthetic gas scavenging systems) (class IIa)
 - PF-02Ex-yyyy Outlets for terminal units for AGSS
 - PF-01Ex-yyyy Base blocks for terminal units for AGSS
 - PF-06Ex-yyyy Probes for terminal units for AGSS
 - KT-02Ex-yyyy Replacement kits for terminal units for AGSS
 - PF-76xx-yyyy Accessories for AGSS

- Flow-meters for connection with terminal units of medical gas pipeline systems (class IIa)
 - PF-26xx-yyyy Flow meters
 - PF-27xx-yyyy Humidifiers for flow meters
 - PF-57xx-yyyy Flow selectors

- Medical suction devices
 - PF-38xx-yyyy Vacuum regulators with collection for collection jar or hose barb fitting (class IIa)
 - PF-50xx-yyyy Vacuum regulator – Probe – Flexible hose kit – Hose barb fitting/collection jar – filter (class IIb)

- Shut-off area valves and Vacuum control units (class IIb)
 - PF-03xx-yyyy Shut-off area valves for medical gases and vacuum
 - PF-35xx-yyyy Vacuum control units
 - PF-45xx-yyyy Area valves pre-assembled cabinets
 - PF-46xx-yyyy Shut off valves pre-assembled cabinets for fire control
 - PF-48xx-yyyy Shut off line valves pre-assembled cabinets
 - PF-49xx-yyyy Medical gas distribution system management cabinet
 - PF-61xx-yyyy Shut-off area valves for medical gases and vacuum
 - PF-64xx-yyyy AVSU (Area Valve Service Unit)
 - KT-61xx-yyyy Maintenance kits for shut-off area valves
 - PF-74xx-yyyy Area shut-off valves for compressed medical gases and vacuum
 - KT-74xx-yyyy Connecting kits for area shut-off valves PF-74xx-yyyy
 - KT-76xx-yyyy Maintenance kits for area shut-off valves PF-74xx-yyyy

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Annex 1 to the Certificate n° 063-00-00-DM

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- High pressure systems (class IIb)
 - PF-40xF-yyyy Pigtails for cylinders
 - PF-40xP-yyyy Pigtails for cylinder bundles
 - PF-40xT-yyyy High pressure flexible connections
 - PF-42xy-zzzz Cylinder manifolds

- First stage regulation devices (class IIb)
 - PF-43xx-yyyy First stage regulators for medical gas cylinder manifolds
 - KT-43xx-yyyy Maintenance kits for first stage pressure regulators
 - PF-51xx-yyyy Automatic change-over decompression units for medical gases
 - PF-52xx-yyyy Automatic change-over
 - PF-53xx-yyyy Emergency decompression units for medical gases
 - PF-62xx-yyyy First stage regulators for medical gas cylinder manifolds
 - KT-62xx-yyyy Maintenance kits for first stage pressure regulators
 - PF-70xx-yyyy High-flow manual change-over safety decompression station for medical gases

- Double-stage regulation devices (class IIb)
 - PF-54xx-yyyy Double-stage decompression units for medical gases
 - PF-56xx-yyyy Double-stage emergency decompression units for medical gases
 - PF-59xx-yyyy HTM 02-01 automatic manifolds for medical gases
 - PF-60xx-yyyy HTM 02-01 emergency reserve manifolds for medical gases

Milan, 2019-05-24

dr. ing. Roberto Cusolito

Managing Director