



DNV BUSINESS ASSURANCE

PRODUCTION QUALITY MANAGEMENT CERTIFICATE/ TECHNICAL ASSESSMENT CERTIFICATE FOR AN INTERMEDIATE STAGE OF MANUFACTURE

Certificate No. 134571-2013-CE-ITA-NA

This Certificate consists of 1 pages

This is to certify that the Quality Management System of

CAMOZZI S.P.A

Via Eritrea, 20/I - 25126 Brescia, Italy

for production and final product inspection/testing of

Pressure control valve for fluids in haemodialysis equipment

has, on a voluntary basis, been assessed with respect to

the CAM D conformity assessment procedure, including relevant requirements for documentation specified in Annex VII, section 3 of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

Further details are given overleaf

Place and date:

Høvik, 03 May 2013

This Certificate is valid until:

03 May 2018

For DET NORSKE VERITAS CERTIFICATION AS
Norway



Aud Løken Eiklid
Certification Manager

Mitra Salim
Technical Reviewer

Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info

If any person suffers loss or damage which is proved to have been caused by any negligent act or omission of Det Norske Veritas, then Det Norske Veritas shall pay compensation to such person for his proved direct loss or damage. However, the compensation shall not exceed an amount equal to ten times the fee charged for the service in question, provided that the maximum compensation shall never exceed USD 300.000. In this provision "Det Norske Veritas" shall mean the Foundation Det Norske Veritas as well as all its subsidiaries, directors, officers, employees, agents and any other acting on behalf of Det Norske Veritas.



Cert. No.: 134571-2013-CE-ITA-NA
Rev. No.:
Project No.: PRJC-353318-2011-MSL-ITA

Certificate history

Revision	Description	Issue Date
	Original Certificate	2013-05-03

Products covered by this Certificate

Product Description
Pressure control valve for fluids in haemodialysis equipment



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Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the local DNV Office of any intended updating of the quality system and DNV will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system DNV reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Declaration and marking of product

This Certificate and the related assessment activities are intended to increase the confidence of the manufacturer and other stakeholders that the requirements of the stated scheme are met.

It is still the full responsibility of the manufacturer to make sure that every product under this Certificate complies with the scheme.

END OF CERTIFICATE