



DNV BUSINESS ASSURANCE

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 16660-2007-CE-NOR Rev. 4.0
This Certificate consists of 4 pages

This is to certify that the Quality Management System of
Medical Components Inc. (dba Medcomp)
Harleysville, USA

for design, production and final product inspection/testing of

Long Term Haemodialysis Catheters, Peritoneal Catheters and Accessories

has been assessed with respect to
the conformity assessment procedure described in Article 11.1.a and Annex II (Module H1), Article 11.3.a
and Annex II excl. section 4 (Module H), Article 11.2.b and Article V (Module D1)
of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

Further details are given overleaf

Place and date:
Høvik, 24 October 2013

For DET NORSKE VERITAS CERTIFICATION AS
Norway



This Certificate is valid until:
01 October 2018



Jenny Helen Nytnun
Certification Manager

Notified Body No.:
0434

Aud Løken Eiklid
Technical Reviewer

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



Cert. No.: 16660-2007-CE-NOR
 Rev. No.: 4.0
 Project No.: PRJC-38025-2007-PRC-USA

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift for Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history

Revision	Description	Issue Date
	Original Certificate	2008-01-01
1.0	Recertification	2008-10-17
2.0	Products Dynamic Flow and More Flow removed	2010-03-17
3.0	Product Ultra Flow removed	2010-08-16
4.0	Re-Certification	2013-10-01

Products covered by this Certificate

Product Description	Product Name	Class
Long Term Haemodialysis Catheters, Peritoneal Catheters and Accessories	<ul style="list-style-type: none"> • Cuffed or Security Anchored Long Term Haemodialysis Catheters <ul style="list-style-type: none"> • Tesio® Catheters (Silicone or Polyurethane) • Tesio® Catheter without Sideholes • TriniFlex™ Tesio® with stylet • Hemo-Cath® (Silicone) • Schon Cath® (Silicone) • Split Cath® (Polyurethane) • Dura-Flow® (Polyurethane) • Split Stream® (Polyurethane) • PolySchon Cath (Polyurethane) • Hemo Flow (Polyurethane) • Chronic TwinLine (Polyurethane) • Titan HD™ Catheter (Polyurethane) • 15.5 F Free Flow Coaxial (Polyurethane) • Canaud-Cath (Silicone) • Catheter Repair Kits 	III*
	<ul style="list-style-type: none"> • Peritoneal Catheter 	I Ib
	<ul style="list-style-type: none"> • Kit Accessories <ul style="list-style-type: none"> • Extension Sets • Dilator 	I Ia

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

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.



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Long Term Haemodialysis Catheters, Peritoneal Catheters and Accessories continues	<ul style="list-style-type: none"> • Gloves • Guidewire • Introducer Catheters • Needles • Scalpels • Syringes • Tunneler • Sutures 	
	<ul style="list-style-type: none"> • Kit Accessories <ul style="list-style-type: none"> • Caps and Plugs • Clamps • Dressing • Suture wing and Anchoring Devices • Drape • Wrap • Scissors • Tourniquet • Gauze 	I sterile

* Design assessment is covered by a separate design examination certificate no 16660-2007-CE-NOR-D

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

1499 Delp Dr., Harleysville, PA 19438, USA

Authorized Representative

MPS Medical Product Service GmbH
 Borngasse 20, 35619 Braunfels, Germany

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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.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of DNV.

END OF CERTIFICATE

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