DET NORSKE VERITAS

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 66510-2009-CE-ITA-NA 3.0
This Certificate consists of 4 pages

This is to certify that the Quality Management System of

ANGELANTONI INDUSTRIE S.P.A.

Località Cimacolle, 464, 06056, Massa Martana, Italy

for design, production and final product inspection/testing of

Human Tissues Cooling Units

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

Further details are given overleaf

Place and date:
Høvik, 15 August 2011

For DET NORSKE VERITAS CERTIFICATION AS
NORWAY

Aud Løken Eiklid
Certification Manager

NORWEGIAN ACCREDITATION
PROD 002

CE

Notified Body No.:
0434

This Certificate is valid until:
14 December 2014

Jenny Helen Nytun
Technical Reviewer

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

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	2009-12-14
1.0	New devices added	2011-02-11
2.0	New devices added	**2011-07-19**
3.0	**New devices added (in Bold)**	**2011-08-15**

Products covered by this Certificate

Product Description	Product	Class
Blood and Blood Cells Cooling Units	Blood Banks • BBR • MINI • HEMONINE • HEMOSAFE	IIa
Human Tissues (Blood, blood cells, tissues and fluids) Cooling Units	Freezers • PLASMAFROST • **PLASMAFROST 3 ITEM** • **PLASMAFROST 4 ITEM** • PLATINUM • IRIDIUM • PLATINUM NEXT • IRIDIUM NEXT • KRYOS MD 500 SV • KRYOS MD 500 SV plus	IIa

Human Tissues (Blood, blood cells, tissues and fluids) Cooling Chambers	Refrigeration Chambers • PE2003 TN-MD single refrigeration group • PE2004 TN-MD single refrigeration group • PE2005 TN-MD single refrigeration group • PE2006 TN-MD single or double refrigeration group • PE2610 TN-MD single or double refrigeration group • PE2615 TN-MD single or double refrigeration group • PE2621 TN-MD single or double refrigeration group • PE2621 TN	IIa
Human Tissues (Blood, blood cells, tissues and fluids) Freezer Chambers	Freezer Chambers • PE2103 LT-MD single refrigeration group • PE2104 LT-MD single refrigeration group • PE2105 LT-MD single refrigeration group • PE2106 LT-MD single or double refrigeration group • PE2610 LT-MD single or double refrigeration group • PE2615 LT-MD single or double refrigeration group • PE2619 LT-MD single or double refrigeration group • PE2619 BT	

The complete list of devices is filed with the Notified Body.

Sites covered by this certificate

Site Name	Address
ANGELANTONI INDUSTRIE S.p.A. - Sede legale e operativa	Località Cimacolle, 464 - 06056, Massa Martana, Italy

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