



EC Certificate Production Quality Assurance

Certificate No.: EU1502403
Order No.: 279173

Date: 2015-02-13

We hereby certify that an examination has been carried out following the requirements of the national legislation "Regulation no. 1690 of 15th December 2005 relating to medical devices pursuant to act no. 6 of 12th January 1995 relating to medical devices, transposing directive 93/42/EEC into Norwegian law to which the undersigned is subjected, confer EEA agreement, proposition no. 100 (1991-92) special appendix no. 2, volume 2A/3 A, goods, chapter XXX". We certify that the production quality system conforms to the relevant provisions of the Annex given below:

Manufacturer:	ARCTIKO A/S Lammefjordvej 5 Esbjerg N, 6715 Denmark
Device categorie(s):	MD 1101 Blood bank refrigerator
GMDN code:	See page 2 to this certificate
Models:	See page 2 to this certificate
Risk class as defined by the manufacturer:	Ila
Standards/provisions:	The audit of the quality system was based upon and assessed according to the provisions in Annex V of the EC-Directive 93/42/EEC.
Date of audit:	2014-09-25/26
End of the validity:	2020-03-01
Nemko EC notification No.:	0470
Remarks:	-

On this basis the manufacturer or the European authorised representative may draw up an EC / EEA Declaration of Conformity and affix the CE-marking as indicated below together with the Nemko EC notification number to each conforming product as long as the conformity audit and inspection procedure required by the EC directive will be fulfilled by the manufacturer and the factory. The product liability rests with the manufacturer or his representative in accordance with Council Directive 85/374/EEC.

Arild R. Hansgård
For Nemko AS



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Lammefjordvej 5
Esbjerg N, 6715
Denmark

Certificate History:

Revision	Description	Issue Date
0	Certification	2015-02-13

The certificate referred to above, includes the following devices/models:

Device Category	Model Name	GMDN Code
MD 1101 Blood bank refrigerator	BBR100, BBR300, BBR500, BBR700, BBR1400, BBR100-D, BBR300-D, BBR500-D, BBR700-D, BBR1400-D	35486