

EC Declaration of conformity

MANUFACTURER (FABRIKANT):

ARCTIKO A/S

ADDRESS (ADRESSE):

ODDESUNDVEJ 39,
6715 ESBJERG, DENMARK
SRN: DK-MF-000027388

PRODUCT (PRODUKT) INFORMATION:

BBR 100 / BBR 100-D / BBR 300 / BBR 300-D / BBR 500 /
BBR 500-D / BBR 700 / BBR 700-D / BBR 1400 / BBR 1400-D

TYPE (MODEL):

BLOOD BANK REFRIGERATOR

CLASS & CONFORMITY ASSESSMENT (KLASSE & OVERENSSTEMMELSESGEDELSE)

CLASS

CLASS IIA RULE 2, ANNEX IX

CONFORMITY ASSESSMENT

CONFORMITY ASSESSMENT PROCEDURE, ANNEX V

NOTIFIED BODY:

DNV PRODUCT ASSURANCE AS - NB2460

WE HEREBY DECLARE THAT THE **ABOVE MENTIONED** PRODUCTS COMPLY WITH THE FOLLOWING DIRECTIVES, NATIONAL LAWS AND HARMONIZED STANDARDS:

(VI ERKLÆRER HERMED, AT OVENSTÅENDE PRODUKT ER I OVERENSSTEMMELSE MED FØLGENDE EU DIREKTIV(-ER), RELEVANT GÆLDENDE DANSK LOVGIVNING OG HARMONISEREDE STANDARDER)

EUROPEAN MEDICAL DEVICE DIRECTIVE 93/42/ EEC WITH AMENDMENT 2007/47/EC ROHS DIRECTIVE 2011/65/EU

HARMONIZED STANDARDS (HARMONISEREDE STANDARDER):

European Medical Device Directive 93/42/ EEC with amendment 2007/47/EC

EN 60601-1:2006+A11:2011 + A1:2013

Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.

EN 60601-1-2:2015

Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.

EN 62366:2008

Medical devices – Application of usability engineering to medical devices.

EN ISO 14971:2019

Medical devices - Application of risk management to medical devices.

EN ISO 13485:2016

Medical devices - Quality management systems - System requirements for regulatory purposes.

EN 378-1:2016 & DS/EN 378-2:2016

Refrigerating systems and heat pumps - safety and environments - Part 1: Basic requirements, definitions, classification and selection criteria. Part 2: Design, construction, testing, marking and documentation.

EN 14276-2+A1:2011 clause 8.9.4.1.2

Pressure equipment for refrigerating system and Heat pumps Part 2: piping – general requirements.



Esbjerg 16/08/2022

City & DD/MM/YYYY

5082052-12

Name & position

Tove Tækker Svendsen
R&D & QA Manager