DNV·GL

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
241154-2017-CE-ITA-NA-PS Rev. 4.0	PRJC-403782-2012-MSL-ITA	26 May 2024

This is to certify that the quality system of:

ANGELANTONI LIFE SCIENCE S.r.l.

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 IN ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 08 May 2020

Digitally signed by Ciobanu Sergiu
Date: 2021.10.21 08:41:09 EEST
Reason: MoldSign Signature
Location: Moldova

NORWEGIAN ACCREDITATION

PROD 021

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Tone Kolpus

Tone Elise Kolpus

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

Jurisdiction

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

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate - Replaces Certificate 66510-2009-CE-ITA-DNV Rev. 5.0 (NB 0434), following transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460)	2017-10-30
1.0	Blood Banks: - Deletion of discontinued Devices - Hemonine, Hemosafe, Plasmafrost; Refrigeration Chambers (all); Freezer Chambers (all) ; - New device added: Hemosafe 2.0 - Unmerging Blast Freezers from Freezers	2018-10-11
2.0	Blood Banks: - New devices added Emobanks & Plasmabanks (EB&PB) - Deletion of discontinued Devices - MINI, BBR	2019-11-19
3.0	Renewal Freezer - New devices added Nexus Evo, Smart Freezer Evo Deletion of discontinued Devices - Platinum, Iridium, PlatinumNext, IridiumNext, Kryos MD	2019-12-19
4.0	**Device list added**	2020-05-07

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Products covered by this Certificate:

Product Description	Product Name	Class
Blood and Blood Cells Cooling Units	BLOOD BANKS Number — Device model name 14214 — HEMOSAFE 2.0 14361 — EMOBANK 100/2 14362 — EMOBANK 200/3 14363 — EMOBANK 200/4 14364 — EMOBANK 300/5 14365 — EMOBANK 300/6 14366 — EMOBANK 700 B 14367 — EMOBANK 700/5 14368 — EMOBANK 700/6 14369 — EMOBANK 700/7 14370 — EMOBANK 700/8 14371 — EMOBANK 900 B 14372 — EMOBANK 900/8 14373 — EMOBANK 900/9 14374 — EMOBANK 1500 B 14375 — EMOBANK 1500/12 14376 — EMOBANK 1500/14 14386 — EMOPLASMABANK 300 14387 — EMOPLASMABANK 700 14388 — EMOPLASMABANK 1500	IIa

Human Tissues (Blood, blood cells, tissues and fluids) Cooling Units	PLASMA FREEZERS Number — Device model name 14417 — NEXUS 518 SV EVO MD 14421 — NEXUS 110 SH EVO MD 14422 — NEXUS 370 SH EVO MD 14423 — NEXUS 550 SH EVO MD 14424 — NEXUS 340 SV-3 EVO MD 14425 — NEXUS 340 SV-4 EVO MD 14426 — NEXUS 530 SV-3 EVO MD 14427 — NEXUS 530 SV-4 EVO MD 14428 — NEXUSSlim 810 SV-4 EVO MD 14429 — NEXUSSlim 810 SV-5 EVO MD 14430 — NEXUS 110 H EVO MD 14431 — NEXUS 370 H EVO MD 14432 — NEXUS 550 H EVO MD 14434 — NEXUS 340 V-3 EVO MD 14435 — NEXUS 340 V-4 EVO MD 14436 — NEXUS 530 V-3 EVO MD 14437 — NEXUS 530 V-4 EVO MD 14438 — NEXUSSlim 810 V-4 EVO MD 14439 — NEXUSslim 810 V-5 EVO MD 14381 — PLASMABANK 700 LT 14382 — PLASMABANK 900 LT CRYOBANK 14327 — Smartfreezer EVO MD V.180.10 14328 — Smartfreezer EVO MD V.180.20	IIa
Human Tissues (Plasma) Fast Cooling Chambers	BLAST FREEZERS Number — Device model name 13368 — PLASMAFROST 3 ITEM 13204 — PLASMAFROST 4 ITEM	IIa

Sites covered by this certificate

Site Name	Address
ANGELANTONI LIFE SCIENCE S.r.l.	Località Cimacolle, 464 06056 MASSA MARTANA

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 Presafe of any intended updating of the quality system and Presafe 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. Presafe 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 Presafe.

End of Certificate