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Biosafe S.A.

DECLARATION OF CONFORMITY

Following the provisions of the medical devices directive 93/42/EEC, Annex VII.

We:

Manufacturer

Biosafe S.A.
Route du Petit-Eysins 1
1262 Eysins, Switzerland

EU Authorized Representative

Qarad EC-REP BV
Pas 257
2440 Geel, Belgium

Declare under our sole responsibility that the device:

FREEZING BAG FB-100.X

A durable, sterile plastic container with ports, or glass bottle, intended for the storage and/or culture of tissue, cells, blood or blood components (e.g., peripheral blood stem cells) typically for subsequent therapeutic applications. The device provides a suitable closed environment to reduce the risk of contamination and, if applicable, for cell growth/viability during storage that may or may not involve freezing. A device intended for cryopreservation is typically designed for long-term storage in a freezing system. A device intended for culture is typically gas permeable and may have an inner surface that enables adherence. This is a single-use device.

Ref:

Medical Device Name	Medical Device Reference	Catalog Designation
CryoSC-S freezing bag	FB-100.1	10023
CryoSC-D freezing bag	FB-100.2	10032
CryoSC-Db freezing bag	FB-100.2b	10041

GMDN Code: 44904

Classification rule (93/42/EC Annex IX) 18 Class IIb

To which this declaration relates, is in conformity with the requirements of the medical devices directive 93/42/EEC that apply to it.

This conformity is based on the following elements:

- For the directive 93/42/EEC (MDD)
  - Technical Documentation/DHF Ref./ réf: Technical File 06 (Freezing bag), of the product to which this declaration relates.
  - ISO 13485 Certificate: Approval of Quality Assurance System delivered by TÜV SÜD PRODUCT SERVICE GMBH on 06-07-2018/ Certificate N Q5 1804 45171 022
  - Harmonized standards applied on the product to which this declaration relates; see Addendum.

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SIGNATURE:

Date of issue:	06-AUG-2021
Place of issue:	Eysins
Name:	Alison Campbell
Function:	Total Quality Leader - PRRC
Signature:	A Campbell

ADDENDUM TO THE DECLARATION OF CONFORMITY 29468717

Standard
EN ISO 14971 :2019 Medical devices – application of risk management to medical devices
EN ISO 15223-1:2016 Medical devices – symbols to be used with medical device labels, labelling and information to be supplied – part 1: general requirements medical devices – symbols to be used with medical device labels, labelling and information to be supplied – part 1: general requirements
EN 1041 :2008 +A1: 2013 Information supplied by the manufacturer of medical devices
ISO 11135 :2014 +AMD1: 2018 Sterilization of health-care products -- ethylene oxide -- requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 11737-1 :2018 Sterilization of medical devices -- microbiological methods -- part 1: determination of a population of microorganisms on products
EN ISO 11607-1 :2020 Packaging for terminally sterilized medical devices -- part 1: requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2 :2020 Packaging for terminally sterilized medical devices - part 2: validation requirements for forming, sealing and assembly processes
EN 556-1:2001/AC :2006 Sterilization of medical devices – requirements for medical devices to be designated 'sterile' - part 1: requirements for terminally sterilized medical devices
EN ISO 80369-7:2017Conical fittings with 6 % luer taper for syringes, needles and certain other medical equipment
ISO 14644-1 :2015 Cleanrooms and associated controlled environments - part 1: classification of air cleanliness by particle concentration
EN-ISO 10993-1 :2020 Biological evaluation of medical devices - part 1: evaluation and testing
EN-ISO 10993-4 :2017 Biological evaluation of medical devices - part 4: selection of tests for interactions with blood
EN ISO 10993-5 :2009

Biological evaluation of medical devices - part 5: tests for in vitro cytotoxicity
EN ISO 10993-7 :2008/AC: 2009 Biological evaluation of medical devices - part 7: ethylene oxide sterilization residuals
ISO 10993-10 :2010 Biological evaluation of medical devices - part 10: tests for irritation and skin sensitization
EN ISO 10993-11 :2018 Biological evaluation of medical devices - part 11: tests for systemic toxicity
EN-ISO 10993-12 :2012 Biological evaluation of medical devices - part 12: sample preparation and reference materials
EN ISO 10993-18: 2009 Biological evaluation of medical devices - part 18: chemical characterization of materials

End of Document