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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:

COLLECTION BAG RCA-100

A sterile collection of instruments, pharmaceuticals, and other items intended for use in combination to collect and/or deliver bone marrow. This is a single-use device.

Ref:

Medical Device Name	Medical Device Reference	Catalog Designation
Collection bag	RCA-100	4212

GMDN Code: 33984

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 07 (RCP100-RCA100), 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.

SIGNATURE:

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

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ADDENDUM TO THE DECLARATION OF CONFORMITY 29468973

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 Information supplied by the manufacturer of medical devices
ISO 11135 :2014 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 :2006/AC:2009 Sterilization of medical devices -- microbiological methods -- part 1: determination of a population of microorganisms on products
EN ISO 11607-1 :2009 Packaging for terminally sterilized medical devices -- part 1: requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2 :2006 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 20594-1 :1993/A1 :1997 Conical 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 :2009/AC:2010 Biological evaluation of medical devices - part 1: evaluation and testing
EN-ISO 10993-4 :2009 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 :2009 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