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Biosafe S.A.

DECLARATION OF CONFORMITY

Following the provisions of the medical devices directive 93/42/EEC, Annex II and of the directive 2011/65/EU.

We:

Manufacturer

BIOSAFE S.A
Route du Petit-Eysins 1
1262 Switzerland

EU Authorized Representative

Qarad EC-REP BV
Pas 257
2440 Geel, Belgium

Declare under our sole responsibility that the device:

Sepax™ S-100 (Sepax 2 S-100)

A mains electricity (AC-powered) portable device that is a component of a blood centrifugation system designed for the automated processing of blood, relative components or cellular products (e.g., umbilical cord blood, bone marrow), in a closed sterile environment using centrifugation to isolate constituent components (e.g., cells, plasma). It is a programmable device with an integral centrifuge intended to provide centrifugal and axial displacement drive to a centrifugation chamber, as well as drive to directional valves that control the flow of blood components to collection bags. The device is not donor or patient connected.

Ref:

Medical Device Name: Sepax™ S-100	
Medical Device Reference	**Catalog Designation**
Sepax S-100	14000

GMDN Code: 60334 UDI-DI code: N/A

Classification rule (93/42/EC Annex IX) 3 Class IIa

To which this declaration relates, is in conformity with the requirements of the medical devices directive 93/42/EEC that apply to it and with the requirements of the directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

This conformity is based on the following elements:

- For the directive 93/42/EEC (MDD)
  - Technical Documentation/DHF Ref./ réf: Technical File 04 (Sepax RM200), of the product to which this declaration relates
  - EC Certificate: Approval of full quality assurance system (Annex II of the medical devices directive 93/42 EEC) delivered by TÜV SÜD PRODUCT SERVICE GMBH (Notified Body 0123) on 24-05-2018 / Certificate N G1 18 05 45171 024
    - Address: Ridlerstrasse 65, 80339 München, Germany
  - Harmonized standards applied on the product to which this declaration relates, see Addendum
- For the directive 2011/65/EU (RoHS) including amendment of Annex II (2015/863)
  - Technical Documentation/DHF Ref./ réf: Technical File 04 (Sepax RM200), of the product to which this declaration relates

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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 29467631

Sepax S-100 (Sepax 2) – Accessories and Components

Medical Accessories	Catalog Designation
CS-XXX.X Sepax Cell Separation kit	Depending on the kits reference

Biosafe S.A has verified the mutual compatibility of the accessories in combination with Sepax S-100 (Sepax 2) and included relevant information to users with Sepax S-100 (Sepax 2) instructions for use. This activity was subject to appropriate methods of internal control and inspection.

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 60601-1:2006/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 disturbances - requirements and tests
EN 60601-1-6: 2010 Medical electrical equipment - part 1-6: general requirements for basic safety and essential performance - collateral standard: usability
EN 1041:2008 Information supplied by the manufacturer of medical devices
EN 62471:2008 Photobiological safety of lamps and lamp systems
IEC 62304:2006/Amd 1:2015 Medical device software – software life cycle processes
EN 60529:1991/A2:2013 Degrees of protection provided by enclosures

Directive
WEEE Directive (2012/19/EU): Waste of Electrical and Electronic Equipment Directive

End of Document