cytiva

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™ RM (Sepax 2 RM)

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™ RM	
Medical Device Reference	**Catalog Designation**
Sepax RM	14100

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 RM 200), of the product to which this declaration relates

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 29467630

Sepax 2RM – 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 2RM and included relevant information to users with Sepax 2RM 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