EU DECLARATION OF CONFORMITY

Following the provisions of the medical devices regulation 2017/745.

We:

Manufacturer	EU Authorized Representative
BIOSAFE S.A Route du Petit-Eysins 1 1262 Switzerland	Qarad EC-REP BV Pas 257 2440 Geel, Belgium SRN: BE-AR-000000040

Declare under our sole responsibility that the device:

Name: 1. SMART-MAX AS-310
2. Smart-Max applications (accessories):
2.1. Cryo-SC Smart-Max protocol software
2.2. Thaw-SC Smart-Max protocol software
2.3. Cryo-Large Volume Smart-Max protocol software
3. Bag pole accessory for Cryo-Large Volume

Basic UDI-DI: Smart-Max: 764012565CRTH01ACTVNW
Smart-Max applications: 764012565CRTH01APPLPX
Bag pole: 764012565CRTH01ACSRNK

Identification number: Smart-Max: 3500
Cryo-SC application: 3702
Thaw-SC application: 3801
Cryo-Large Volume application: 29271077
Bag pole: 3598

Intended Purpose:

- Smart-Max: is intended for use in the processing of blood, blood derivatives or cellular products in order to cryo-prepare, thaw, incubate or inject biological products for medical purpose. The Smart-Max device is intended for the safe and reproducible mixing of bag(s) under regulated temperature (cooling or heating) and / or injection of biological additives into the bag at a controlled rate
- Cryo-SC: is an application intended to prepare a unit of umbilical cord blood for cryo-storage.
- Thaw-SC: is an application intended to defrost reduced volume units of cord blood in a closed and controlled environment, without the use of water or any other solutions.
- Cryo-Large Volume: is an application intended to prepare a unit of cellular products for cryo-storage
- Bag pole: is an accessory dedicated for the application Cryo-Large Volume. This accessory is intended to hold the bag or the container containing the cryoprotectant solution (e.g. DMSO) during the procedure of cryopreparation (cooling and cryoprotectant addition to cord blood).

GMDN Code: Smart-Max and bag pole: 60262
Smart-Max applications: 60262
EMDN Code: Smart-Max and Smart-Max applications: B06
Bag pole: B0180

Class: I

Classification rule (Annex VIII): Smart-Max: 11 & 13
Smart-Max applications: 1
Bag pole: 1

To which this declaration relates is in conformity with the requirements, that apply to it, of the:

- Medical Devices Regulation 2017/745
- Machinery Directive 2006/42/EC;
- RoHS Directive 2011/65/EU including amendment of Annex II (2015/863);
- WEEE Directive (2012/19/EU): Waste of Electrical and Electronic Equipment

This conformity is based on the following elements:

- Technical Documentation reference: TF-08 (Smart-Max AS-310), of the product to which this declaration relates.
- EC certificate N: Not applicable to Class I

- List of Standards applied and in relation to which conformity is declared:

General Safety:

- EN ISO 14971:2019
- EN 62304:2006+A1:2015*
- EN 62471: 2008
- IEC 62366-1: 2015

*NA for accessories

Environmental :

- EN IEC 63000 :2018

EMC*:

- EN 60601-1-2: 2015

Electrical Safety*:

- EN 60601-1: 2006+A1:2013
- EN 60601-1-6: 2010

SIGNATURE:

Date of issue:	09-AUG-2021
Place of issue:	Eysins
Name:	Alison Campbell
Function:	Total Quality Leader - PRRC
Signature:	A Campbell

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