

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: Metal Storage Canister
CryoSC-Db Seal Positioner
Press Modular
Kit Connector
Separation Chamber Holder

Basic UDI-DI: CryoSC-Db seal positioner, metal storage canister: 764012565BLCR01ACSRCK
Kit connector, Press Modular, Separation Chamber Holder: 764012565CESE01ACSRB2

Identification number: Metal Storage Canister: 7012,
CryoSC-Db Seal Positioner: 7035
Press Modular: 7040
Kit Connector: 7033
Separation Chamber Holder: 6033

Intended Purpose:

- Kit Connector: is an accessory for the medical device Modular kits, used with the Press Modular accessory to facilitate and check the connection of the separation chamber to the harness before processing
- Press Modular: is an accessory for the medical device Modular kits, requested to be used with the Kit Connector accessory to facilitate the connection of the separation chamber to the harness before processing.
- Separation Chamber Holder: is an accessory for the medical device CS-900.2 single-use kit, requested to be used for the final steps of the NeatCell, Adipose and CultureWash applications in case the small volume (less than 20 mL) option is chosen. The Separation Chamber Holder accessory is intended to hold the separation chamber upside down in order to facilitate the cells' extraction once the procedure is done.
- Metal Storage Canister: is an accessory for the medical devices Freezing bags (FB-100.X), requested to be used with the Overwrap Bag accessory to enhance the thermal conductivity and have a homogeneous freezing (< -150°C) of the product.
- CryoSC-Db Seal Positioner: is an accessory for the medical devices Freezing bags (FB-100.X), requested to be used to calibrate the volume in each compartment and ensure the sealing of the sampling segments and the sealing between compartments, if a double bag is used.

GMDN Code: CryoSC-Db seal positioner, Metal Storage Canister: 44904

Kit Connector, Press Modular, Separation Chamber Holder: 45669

EMDN Code: CryoSC-Db seal positioner, Metal Storage Canister, Kit Connector, Press Modular, Separation Chamber Holder: B0180

Class: I

Classification rule (Annex VIII): 1 for all the accessories

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

- Medical Devices Regulation 2017/745;
- Regulation 1907/2006 (EC) (REACH);
- Waste framework directives (2008/98/EC & 2018/851/EC)

This conformity is based on the following elements:


- Technical Documentation reference: TF-05 (05_Accessories Class I), 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

- IEC 62366-1: 2015

SIGNATURE:

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

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