cytiva

**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:

SMART-MAX™ EXTENSION LINE FA-100.2

A sterile length of flexible tube, typically made of synthetic polymer material(s), intended to be used with a cooling laboratory mixer to facilitate the transfer of fluids (e.g., cryopreservation solution) from a solution bag to the destination compartment in the mixer [typically an umbilical cord blood (UCB) unit bag]. It includes connectors at each end (e.g., Luer-lock) that create a closed-circuit for fluid transfer which is promoted by the mixer (e.g., via a peristaltic pump). This is a single-use device.

Ref:

| Medical Device Name | Medical Device Reference | Catalog Designation |
|---|---|---|
| SMART-MAX™ EXTENSION LINE | FA-100.2 | 10048 |

GMDN Code: 61789

Classification rule (93/42/EC Annex IX) 2 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.

This conformity is based on the following elements:

- For the directive 93/42/EEC (MDD)
  - Technical Documentation/DHF Ref./ réf: Technical File 09, of the product to which this declaration relates
  - SO 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 below or Addendum

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 29469512

| Standard |
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| EN ISO 14971 :2019<br>Medical devices -- Application of risk management to medical devices |
| EN ISO 15223-1 :2016<br>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<br>Information supplied by the manufacturer of medical devices |
| ISO 11135 :2014<br>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<br>Sterilization of medical devices -- Microbiological methods -- part 1: Determination of a population of microorganisms on products |
| EN ISO 11607-1 :2009<br>Packaging for terminally sterilized medical devices -- part 1: Requirements for materials, sterile barrier systems and packaging systems |
| EN ISO 11607-2 :2006<br>P ackaging for terminally sterilized medical devices -- part 1: requirements for materials, sterile barrier systems and packaging systems |
| EN 556-1:2001/AC :2006<br>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<br>Conical fittings with 6 % luer taper for syringes, needles and certain other medical equipment |
| ISO 14644-1 :2015<br>Cleanrooms and associated controlled environments - part 1: Classification of air cleanliness by particle concentration |
| EN-ISO 10993-1 :2009/AC:2010<br>Biological evaluation of medical devices - part 1: evaluation and testing |
| EN-ISO 10993-4 :2009<br>Biological evaluation of medical devices - part 4: selection of tests for interactions with blood |
| EN ISO 10993-5 :2009<br>Biological evaluation of medical devices - part 5: tests for in vitro cytotoxicity |
| EN ISO 10993-7 :2008/AC: 2009<br>Biological evaluation of medical devices - part 7: ethylene oxide sterilization residuals |
| ISO 10993-10 :2010<br>Biological evaluation of medical devices - part 10: tests for irritation and skin sensitization |
| EN ISO 10993-11 :2009<br>Biological evaluation of medical devices - part 11: tests for systemic toxicity |
| EN-ISO 10993-12 :2012 |

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| Biological evaluation of medical devices - part 12: sample preparation and reference materials |
| EN ISO 10993-18: 2009<br>Biological evaluation of medical devices - part 18: chemical characterization of materials |

*End of Document*