

Declaration of Conformity Medical Devices

We hereby declare the CE-marked products, specified below, are covered by the “EC Certificate” reference number 34262, originally added at issuance of Rev.3 on 22 March 2019 and most recently issued as Rev. 6 on 13 September 2021, by GMED S.A.S, Notified Body Identification Number 0459, and conform to the required technical documentation in accordance with the Annex VII of the Council Directive 93/42/EEC and 2007/47/EC, issued 21.9.2007, the “EC-Directive”, being concerning with medical devices.

In addition, we ensure and declare that the aforementioned CE-marked products fall within Class IIa and Is, according to Annex IX, rule 2, and rule 1 and meet the provisions of the EC-Directive which apply to them.

This declaration is based on the application of the Quality System approved for the manufacture and final inspection of the products concerned, in accordance with Annex II of the EC-Directive. The conformity of the production quality assurance set out in Annex II, is described in the said CE marking of Conformity Certificate, issued and delivered by GMED S.A.S.

This Declaration of Conformity covers CryoPur DMSO-based Cryopreservation Solutions along with all variants listed below and the vial spike (VSV) accessory sold separately for use with CryoPur DMSO-based Cryopreservation Solutions and all vial variants.

Part Number	Description	GMDN Code
CD-07	CryoPur-D: 55% DMSO, 5% Dextran-40 w/v, Balance Sterile Water Sterile, Non Pyrogenic, Vial, 7.2ml filled volume	46813
CD-100	CryoPur-D: 55% DMSO, 5% Dextran-40 w/v, Balance Sterile Water Sterile, Non Pyrogenic, Vial, 100ml filled volume	46813
CD-50	CryoPur-D: 55% DMSO, 5% Dextran-40 w/v, Balance Sterile Water Sterile, Non Pyrogenic, Vial, 50ml filled volume	46813
CDS-100A	DMSO/Dextran-40, 55% DMSO / 5% Dextran-40 in 0.9% saline, 100 ml fill volume	46813
CP-10	CryoPur: 100% DMSO, 10ml filled volume	46813
CP-100	CryoPur: 100% DMSO, 100ml filled volume	46813
CP-50	CryoPur: 100% DMSO, 50ml filled volume	46813
CP-50-T	CryoPur: 100% DMSO, 50ml filled volume	46813
CP-70	CryoPur: 100% DMSO, Vial 70ml filled volume	46813
SD-10	10ml syringe of 55% w/v DMSO, 5% w/v Dextran-40 in a sterile water solution w/ stopcock and 15cm of SCD tubing	46813

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Part Number	Description	GMDN Code
SDS-05A-B	5ml syringe of 55% w/v DMSO, 5% w/v Dextran-40 in 0.9% saline solution, with 2ml of air in the syringe w/ stopcock and 15 cm of SCD tubing	46813
SDS-15A-F	15ml syringe of 55% w/v DMSO, 5% w/v Dextran-40 in 0.9% saline solution w/ stopcock and 15cm of SCD tubing	46813
SP-10	10ml syringe of 100% DMSO w/ stopcock and 15cm of SCD tubing	46813
SP-20	20ml syringe of 100% DMSO w/ stopcock and 15cm of SCD tubing	46813
SP-30	30ml syringe of 100% DMSO w/ stopcock and 15cm of SCD tubing	46813
SP-50	50ml syringe of 100% DMSO w/ stopcock and 15cm of SCD tubing	46813
SP-50-4	50 ml syringe of 100% DMSO w/ stopcock adhesive bonded to 15 cm of SCD tubing	46813
VSV	Needle-free vial spike, DMSO-resistant	45520

The primary variations amongst CryoPur products are solution concentrations, containers, tubing sets, and packaging. (Note: DMSO = dimethyl sulfoxide; SCD = sterile connect dock).

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