



EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. Issued To: CE 572880 Preservation Solutions, Inc. 1099 Proctor Drive Elkhorn Wisconsin 53121 USA

In respect of:

CoStorSol, MaPerSol, Belzer UW Cold Storage and Belzer MPS Organ Preservation sterile solution containing Adenosine, Allopurinol and Mannitol.

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

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Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: 2012-07-30

Date: 2017-07-25

Expiry Date: 2022-07-29

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A member of BSI Group of Companies.





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Supplementary Information to CE 572880

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Product	Container Volume	Catalog/Part Number
CoStorSol®	500 mL	PS006CE
CoStorSol®	1000 mL	PS004CE
CoStorSol®	2000 mL	PS007CE
MaPerSol®	1000 mL	PS005CE
Belzer UW [®] Cold Storage Solution	500mL	BTLBUW-500
Belzer UW [®] Cold Storage Solution	1000 mL	BTLBUW-1000
Belzer UW [®] Cold Storage Solution	2000 mL	BTLBUW-2000
Belzer MPS [®] Organ Preservation Solution	1000 mL	BTLBMPS-1000

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Certificate History

Date	Reference Number	Action	
30 July 2012	10123172	First issue.	
27 March 2015	10151632	Change of address.	
	10141213	Addition of 2000mL and 500mL CoStorSol variants. Updated part numbers.	
31 May 2016	10159839	Shelf life extension to 18 months for CoStorSol 500mL, 1L and 2L and MaPerSol 1L.	
06 December 2016	10166972	Addition of distributor branded Belzer UW Cold Storage and Belzer MPS Organ Preservation solution labelling.	
Current	8712138	Renewal.	

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