

EC DECLARATION OF CONFIRMITY

GATAMED TIBBI CIHAZ VE MALZEMELER LIMITED Sirketi

Manufacturer : GATAMED TIBBI CIHAZ VE MALZEMELER LIMITED Sirketi
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Website : https://www.gatamed.com
Product Name : STERILE CRYOPROTECTANT SOLUTION (DMSO)

GMDN Code and the Description	46668-Blood storage solution, multipurpose A blood preservation fluid that is used during the collection and storage of blood and blood components in a healthcare and/or a blood bank facility (typically in a laboratory associated with the collection of blood or during apheresis procedures that result in the collection of blood), to perform more than one blood preservation function such as anticoagulation, provision of blood cell nutritional needs, and/or support during blood freezing. It is supplied in a container (e.g., a polypropylene bag) and is not for direct intravenous infusion. This is a single-use device.
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Classification : Class IIb Annex IX Rule 3
Confirmity Assessment Route : 93/42/EC Annex II excluding Section 4

We, the manufacturer hereby declares that the above-mentioned product complies with the relevant provisions of the European Communities' Council Directive 93/42/EEC dated 14 June 1993, as amended by EC Council Directive 2007/47/EEC and this declaration is issued under the sole responsibility of us.

Relevant Harmonized Standarts			
EN ISO 13485: 2016	EN ISO 14971: 2019	EN 15223-1:2016	EN 1041: 2008
EN ISO 10993-1: 2009/AC:2010	EN ISO 10993-2:2006	EN ISO 10993-3:2014	EN ISO 10993-4: 2017
EN ISO 10993-5:2009	EN ISO 10993-10:2013	EN ISO 10993-11:2018	EN ISO 10993-12:2012
EN ISO 20857:2013			
Other Directives, Regulations and Guidelines			
Meddev 2.7/1 rev.4: 2016	Meddev 2.12-2 rev.2: 2012	93/42/EEC: 2011	
Meddev 2.12-1 rev.8: 2013	NBOG 2010-1: 2010		

Notified Body : SZUTEST UYGUNLUK DEGERLENDIRME A.S.
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Notified Body Identification Number : 2195
Certificate Number : 2195-MED-2112002
Place, Issue Date : Ankara , 05th.10.2020

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