

DECLARATION OF CONFORMITY - MEDICAL DEVICES**Automated Cell Collection products**

MANUFACTURER'S NAME AND ADDRESS	Haemonetics S.A. Signy Centre Rue des Fléchères 6 1274 Signy-Centre Switzerland
AUTHORIZED EUROPEAN REPRESENTATIVE	N/A
NOTIFIED BODY AND IDENTIFICATION NUMBER	TÜV SÜD Product Service GmbH (0123) Zertifizierstelle Ridlerstrasse 65 80339 München Germany

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Automated Cell Collection products

PRODUCT NAME	REORDER NUMBER OR LIST NO.	DEVICE CLASS /RULE	GMDN	UMDNS	IMPLEMENTATION DATE	FACILITY LOCATION(S)
Automated Cell Collection Products (Plasma Therapeutics: Harness sets)						
PLS HARNESS SET	00620-00	IIa/2	47572	10426	2011/07/21	JMS/Indonesia
PLS HARNESS SET	00620-KR	IIa/2	47572	10426	2017/07/13	JMS/Indonesia
PLS HARNESS SET W/DRIP	0620E-00	IIa/2	47572	10426	2006/11/11	JMS/Indonesia
PLS HARNESS SET W/DRIP/LL	0620E-SL	IIa/2	47572	10426	2014/08/25	JMS/Indonesia
CONNECTOR, SPIKE/MALE LL	00621-00	IIa/2	47572	10426	2020/06/10	HAE/Malaysia/Penang
Automated Cell Collection Products (Plasma Therapeutics: Plasma collection bags)						
PLS 3-PRODUCT BAGS	00699-00	Iib/18	47572	10426	2015/03/25	HAE/Malaysia/Penang
PLS BAG W/NaCL SPIKE	692AU-00	Iib/18	47572	10426	2015/03/25	HAE/Malaysia/Penang
PLS BAG W/VAC SAMPLING & NaCL	SC692-00	Iib/18	47572	10426	2015/03/12	HAE/Malaysia/Penang
Automated Cell Collection Products (Plasma Therapeutics: Pre-connected plasma collection sets with blow molded bowls)						
PLS BUNDLED SET W/AIR BAG	00782-00	Iib/18	47572	10426	2015/01/23	HAE/Malaysia/Penang
PLS BUNDLED SET W/SALINE LINE	00783-00	Iib/18	47572	10426	2017/03/20	HAE/Malaysia/Penang

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PLS BUNDLED SET W/VAC	00792-00	Iib/18	47572	10426	2015/04/15	HAE/Malaysia/Penang
PLS 3-BAGS CLOSED SET, BMB	0623E-00	Iib/18	47572	10426	2015/01/26	HAE/Malaysia/Penang
PLASMA SET W/FILTER, BMB	0792P-SL	Iib/18	47572	10426	2015/04/10	HAE/Malaysia/Penang
Automated Cell Collection Products (Red Blood Cell, Plasma Therapeutics)						
RBC & PLS W/FILTER	0947F-00	Iib/18	47572	10426	2015/04/16	HAE/Malaysia/Penang
Automated Cell Collection Products (Red Blood Cell, Platelet Therapeutics)						
PBSC SET (225 mL Latham)	0970E-00	Iib/18	47572	10426	2015/04/21	HAE/Malaysia/Penang
PLT&RBC SET W/PLT&RBC FILTER	949FF-E	Iib/18	47572	10426	2015/03/25	HAE/Malaysia/Penang
PLT&RBC SET W/PLT&RBC FILTER	949FF-P-SL	Iib/18	47572	10426	2015/03/16	HAE/Malaysia/Penang
Automated Cell Collection Products (Platelet, Plasma Therapeutics)						
PLT & PLS SET SINGLE DOSE	0996E-00	Iib/18	47572	10426	2015/06/15	HAE/Malaysia/Penang
PLT & PLS SET SINGLE DOSE	0996E-CN	Iib/18	47572	10426	2021/05/21	HAE/Malaysia/Penang

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PLT & PLS SET DOUBLE DOSE	996E2-00	Iib/18	47572	10426	2015/06/15	HAE/Malaysia/Penang
PLT & PLS SET DOUBLE DOSE	996E2-CN	Iib/18	47572	10426	2021/05/21	HAE/Malaysia/Penang
PLT & PLS SET W/FILTER	997CF-E	Iib/18	47572	10426	2015/03/25	HAE/Malaysia/Penang
PLT & PLS SET W/FILTER	997CF-L	Iib/18	47572	10426	2021/03/31	HAE/Malaysia/Penang
PLT&PLS SET W/FILT & BACT.SAMP	997CF-E-BA	Iib/18	47572	10426	2015/11/20	HAE/Malaysia/Penang
PLT & PLS SET W/FILTER	997CF-E-CN	Iib/18	47572	10426	2021/05/21	HAE/Malaysia/Penang
CONC PLT & PLS SET W/FILTER	998CF-E	Iib/18	47572	10426	2015/03/25	HAE/Malaysia/Penang
CONC PLT & PLS SET W/FILTERS	998CF-FP-SL	Iib/18	47572	10426	2015/03/25	HAE/Malaysia/Penang
CONC PLT & PLS SET W/FILTER	999F-E	Iib/18	47572	10426	2015/03/25	HAE/Malaysia/Penang
PLT & PLASMA SET W/FILTERS	999FF-P-SL	Iib/18	47572	10426	2015/03/25	HAE/Malaysia/Penang
Automated Cell Collection Products (Red Blood Cell Therapeutics)						
RBC De-Glycerol./Cell Wash Set	0235P-00	Iib/18	45520	16857	2015/04/27	HAE/Malaysia/Penang

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<p>CLASSIFICATION (AS DEFINED IN MDD, ANNEX IX)</p>	<p>Class IIa device by Rule 2 in Annex IX of the Council Directive 93/42/EEC of 14 June 1993 amended by Directive 2007/47/EEC of 5 September 2007 concerning medical devices.</p> <p>Class IIa device by Rule 3 in Annex IX of the Council Directive 93/42/EEC of 14 June 1993 amended by Directive 2007/47/EEC of 5 September 2007 concerning medical devices.</p> <p>Class IIb device by Rule 18 in Annex IX of the Council Directive 93/42/EEC of 14 June 1993 amended by Directive 2007/47/EEC of 5 September 2007 concerning medical devices.</p>
	<p>Haemonetics S.A. declares under their sole responsibility that the above mentioned products fall within CLASS IIa and IIb and meet the provisions of Annex II.3 of the European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices which apply to them. The products listed in this Declaration of Conformity comply with the requirements of the product-specific standards as listed in PMX1189.</p> <p>This Declaration is supported by EC Certificate G1 071750 0024 Rev. 00 issued by TÜV SÜD Product Service GmbH, Zertifizierstelle, Ridlerstrasse 65, 80339 München, Germany.</p>
<p>SIGNATURE</p>	<p>Name: Andrew Sette </p> <p>Title: Vice President Quality Assurance and Regulatory Affairs, International</p> <p>Date: 25 May 2021</p> <p>Place: Signy, Switzerland</p>