

DECLARATION OF CONFORMITY - MEDICAL DEVICES

Automated Cell Collection Products (Red Cell, Platelet, Plasma Therapeutics); Blood Management Products (Autologous Cell Salvage, Cell Washing, Suction, Filtering, Rapid Infusion, Freezing & Thawing)

MANUFACTURER'S NAME AND ADDRESS	Haemonetics Corporation 400 Wood Rd. Braintree, MA 02184 USA
AUTHORIZED EUROPEAN REPRESENTATIVE	Haemonetics S.A. Signy Centre Rue des Fléchères 6 1274 Signy-Centre Switzerland
NOTIFIED BODY AND IDENTIFICATION NUMBER	TÜV SÜD Product Service GmbH (0123) Zertifizierstelle Ridlerstrasse 65 80339 München Germany

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PRODUCT NAME	REORDER NUMBER OR LIST NO.	DEVICE CLASS /RULE	GMDN	UMDNS	IMPLEMENTATION DATE	FACILITY LOCATION(S)
ACP®215	02215-110-E 02215-220-E	IIa/3	45519	15114	2001-06-01 2014-11-11	HAE Braintree, MA USA Sanmina/Penang, Malaysia
Cell Saver Elite™ <i>XX=may be regionalized for local language</i>	CSE-E-US CSE-E-IE CSE-E-XX	IIb/11	34863	17537	2010-06-10 2014-11-12	HAE Braintree, MA USA Sanmina/Penang, Malaysia
Cell Saver Elite™+ <i>XX=may be regionalized for local language</i>	CSE-EW-US CSE-EW-IE CSE-EW-XX	IIb/11	34863	17537	2016-10-12	Sanmina/Penang, Malaysia
Cell Saver® 5+	02005-220-EP 02005-110-EP	IIb/11	34863	17537	2004-09-04	HAE Braintree, MA USA
cardioPAT®	02050-XXX	IIb/11	34863	17537	2001-01-19	HAE Braintree, MA USA
MCS®+	08150-220-E	IIb/11	16405	16405	2009-03-20 2014-06-12	HAE Braintree, MA USA Sanmina/Penang, Malaysia

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MCS®+	09000-220-E 09000-220-ED 09000-220-EW 09000-220-EW-RU	IIb/11	16405	16405	1996-01-01 2014-06-24	HAE Braintree, MA USA Sanmina/Penang, Malaysia
OrthoPAT®	1050-240-XXX OPA-E-XX	IIb/11	34863	17537	2001-01-19 2007-09-01	HAE Braintree, MA USA
PCS®2	06002-220-EXP 06002-220-EXP-EW 06002-CP-220 06002-CP-220-EW	IIb/11	16405	16405	1995-08-01 2014-01-27	HAE Braintree, MA USA Sanmina/Penang, Malaysia
PCS®2	06002-CP-220-RU	IIb/11	16405	16405	2014-01-27	Sanmina/Penang, Malaysia
PCS®300 (NexSys PCS™)	PCS-300-INT	IIb/11	16405	16405	2018-02-05 2019-01-25	Sanmina/Penang, Malaysia Plexus/Penang, Malaysia
Smart Suction Harmony®	HAR-E-115-US HAR-E-230-XX	IIa/11	36777	17537	2005-09-05 2015-02-11	HAE Braintree, MA USA Sanmina/Penang, Malaysia

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PRODUCT NAME	REORDER NUMBER OR LIST NO.	DEVICE CLASS /RULE	GMDN	UMDNS	IMPLEMENTATION DATE	FACILITY LOCATION(S)
RBC Bag with Luer Lock, 600mL	00165-00	I Ib/18	17605	17605	2014-01-23	HMM Tijuana Mexico
Waste Bag, 5L	00166-00	IIa/2	17605	17605	2014-01-23	HMM Tijuana Mexico
Y Connector with Check Valve	00167-00	IIa/2	17605	17605	2014-07-30	HMM Tijuana Mexico
Reservoir, Hard-Shell, 150µ	00205-00	IIa/3	17605	17605	2015-05-20	HMM Tijuana Mexico
Aspiration / Anticoagulation Set	00208-00	IIa/2	17605	17605	1997-02-01 2014-07-30	Kawasumi/Thailand HMM Tijuana Mexico
Aspiration & Anticoagulation Line	00208-MT	IIa/2	17605	17605	2015-09-21	HAE Malaysia
Reservoir, Hard-Shell, 40µ	00215-00	IIa/3	17605	17605	2015-11-25	HAE Braintree, MA USA
Reservoir, Hard-Shell, 20µ	00220-00	IIa/3	17605	17605	2015-05-20	HMM Tijuana Mexico
RBC Glycerolization Set	00225-00	IIa/2	45520	16857	2014-11-07	HMM Tijuana Mexico
RBC De-Glycerol. / Cell Wash Set	00235-00	I Ib/18	45520	16857	2014-11-07	HMM Tijuana Mexico
RBC De-Glycerol. Set 325mL BMB	00236-00	IIa/2	45520	16857	2014-11-07	HMM Tijuana Mexico
Y Set with Extension Line	00240-00	IIa/2	17605	17605	2014-01-23	HMM Tijuana Mexico

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PRODUCT NAME	REORDER NUMBER OR LIST NO.	DEVICE CLASS /RULE	GMDN	UMDNS	IMPLEMENTATION DATE	FACILITY LOCATION(S)
Reservoir, Soft Shell, 4µ Filter	00240-MTSA	IIa/3	17605	17605	2015-10-23	HAE Malaysia
Sequestration Set	00244-00	IIb/18	17605	17605	2014-01-23	HMM Tijuana Mexico
RBC Bag w/Twist Lock, 1000mL	00245-00	IIb/18	17605	17605	2014-01-23	HMM Tijuana Mexico
10 Liter Waste Bag	00246-00	IIa/2	17605	17605	2014-01-23	HMM Tijuana Mexico
CS5/5+ Fastpack,225ml,150µ Res	00260-00	IIb/18	17605	17605	2015-05-20	HMM Tijuana Mexico
CS5/5+ Fastpack,225ml, 20µ Res	0260F-00	IIb/18	17605	17605	2015-05-20	HMM Tijuana Mexico
Cell Saver 5/5+ Bowl Kit-125mL	00261-00	IIb/18	17605	17605	2014-01-23	HMM Tijuana Mexico
Cell Saver 5/5+ Bowl Kit-225mL	00263-00	IIb/18	17605	17605	2014-01-23	HMM Tijuana Mexico
CS5/5+ Fastpack,125ml,150µ Res	00265-00	IIb/18	17605	17605	2015-05-20	HMM Tijuana Mexico
CS5/5+ Fastpack,125ml, 20µ Res	0265F-00	IIb/18	17605	17605	2015-05-20	HMM Tijuana Mexico
cardioPAT Post-Op Line	00273-00	IIa/2	17605	17605	2014-04-15	HMM Tijuana Mexico
Cell Saver 5/5+ Bowl Kit-70mL	0291E-00	IIb/18	17605	17605	2014-01-23	HMM Tijuana Mexico

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PRODUCT NAME	REORDER NUMBER OR LIST NO.	DEVICE CLASS /RULE	GMDN	UMDNS	IMPLEMENTATION DATE	FACILITY LOCATION(S)
Reservoir Soft Shell, 170 µFilter	00300-MTSA	IIa/3	17605	17605	2015-10-23	HAE Malaysia
R.I.S.® Sets	00400-00	IIa/3	10447	10447	2000-07-05	HAE Braintree, MA USA
Extension Lines	00401-00	IIa/2	10447	10447	2014-01-23	HMM Tijuana Mexico
PLS Harness Set	00620-CP	IIa/2	47572	47572	2017-12-08 2019-03-05	JMS/Indonesia JMS/Philippines
Plasma Apheresis Bowl	0625B-JE	IIa/3	47572	10426	2016-03-24	HAE Malaysia
BMB PLS Bowls	0625B-00	IIa/3	47572	10426	1993-01-01 2011-03-24 2018-05-10	HAE Leetsdale USA HAE Draper USA HAE Malaysia
HS PLS Bowl	625HS-00	IIa/3	47572	10426	2016-03-29	HAE Malaysia
PLS Bundled Set w/NaCL w/Vac	00627-00	IIb/18	47572	10426	2015-01-14	HAE Malaysia
PLS Bag	00690-00	IIb/18	47572	10426	2015-01-02	HAE Malaysia
PLS Bag with Vac. Sampling	SC690-00	IIb/18	47572	10426	2015-01-02	HAE Malaysia
PLS Bag with NaCL Spike	00692-00	IIb/18	47572	10426	2015-01-02	HAE Malaysia

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PLS Bag w/Vac Samp & NaCl Spike	SA692-00	IIb/18	47572	10426	2016-05-19	HMM Tijuana Mexico
Plasma Bottle w/Saline Adaptor	0694S-00	IIa/2	47572	10426	2002-07-29 2018-11-15	HAE Leetsdale USA HMM Tijuana Mexico
PLS Saline Adaptor	00695-00	IIa/2	47572	10426	1996-07-08 2014-07-22 2016-11-09	HAE Leetsdale USA HMM Tijuana Mexico Kawasumi/Thailand
PCS Bundled Set W/ Filter BMB	0792P-00	IIb/18	47572	10426	2015-01-14	HAE Malaysia
2-RBC Set w/Filter	00832-EF	IIb/18	47572	10426	2013-10-30	HMM Tijuana Mexico
2-RBC Set w/o Filter	00942-00	IIb/18	47572	10426	2014-12-10	HAE Malaysia
TAE Set	00944-00	IIb/18	47572	10426	2014-12-10	HAE Malaysia
PLT&RBC Set w/PLT&RBC Filter	946FF-00	IIb/18	47572	10426	2015-03-14	HAE Malaysia
2-RBC Set w/Filter	0948F-00	IIb/18	47572	10426	2014-12-10	HAE Malaysia
PBSC Set (125mL Latham)	0971E-00	IIb/18	47572	10426	2015-02-24	HAE Malaysia

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PRODUCT NAME	REORDER NUMBER OR LIST NO.	DEVICE CLASS /RULE	GMDN	UMDNS	IMPLEMENTATION DATE	FACILITY LOCATION(S)
Therapeutic Plasma Exchange Sets (TPE) (225 mL Latham)	0980E-00	IIb/18	47572	10426	2015-02-24	HAE Malaysia
Therapeutic Plasma Exchange Sets (TPE) (125 mL Latham)	0981E-00	IIb/18	47572	10426	2015-02-24	HAE Malaysia
PLT & PLS Set w/Filter	994CF-E	IIb/18	47572	10426	2014-12-10	HAE Malaysia
Extended Storage Platelet (ESP) / Plasma Apheresis Set	0995E-00	IIb/18	47572	10426	2012-08-14	JMS/Singapore
PLT & PLS Set Single Dose	0995E-00	IIb/18	47572	10426	2015-06-15	HAE Malaysia
PLT & PLS Set Double Dose	995E2-00	IIb/18	47572	10426	2014-11-26	HAE Malaysia
400 mL RBC Bag	01200-00	IIb/18	17605	17605	2014-07-08	HMM Tijuana Mexico
3 Liter Waste Bag	01300-00	IIa/2	17605	17605	2014-07-08	HMM Tijuana Mexico
Aspiration & Anticoagulation Line	1400T-00	IIa/2	17605	17605	2014-04-15	HMM Tijuana Mexico
OrthoPAT Post-Op Line	01500-00	IIa/2	17605	17605	2014-04-15	HMM Tijuana Mexico
OrthoPAT Integrated Set	1150H-00	IIb/18	17605	17605	2014-07-18	HMM Tijuana Mexico

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Cell Saver Step Down Adapter	ATA-A-1000	IIa/2	17605	17605	2014-07-22	HMM Tijuana Mexico
Waste Bag, 10L	CSE-B-1000	IIa/2	17605	17605	2014-05-01	HMM Tijuana Mexico
Cell Saver Elite Processing Kit (70 mL)	CSE-P-70	IIb/18	17605	17605	2014-05-01	HMM Tijuana Mexico
Cell Saver Elite Processing Kit (125 mL)	CSE-P-125	IIb/18	17605	17605	2014-05-01	HMM Tijuana Mexico
Cell Saver Elite Processing Kit (225 mL)	CSE-P-225	IIb/18	17605	17605	2014-05-01	HMM Tijuana Mexico
CS ELITE FASTPACK,125mL,150U	CSE-FP-125V	IIb/18	17605	17605	2015-05-20	HMM Tijuana Mexico
CS ELITE FASTPACK,225mL,150U	CSE-FP-225V	IIb/18	17605	17605	2015-05-20	HMM Tijuana Mexico
CS ELITE FASTPACK, 225ML, 20U	CSE-FP-225F	IIb/18	17605	17605	2013-11-01	HMM Tijuana Mexico
Sequestration Kit	CSE-SQ-1000	IIb/18	17605	17605	2014-05-01	HMM Tijuana Mexico
cPAT Quick Connect Process Set	CPT-P-274	IIb/18	17605	17605	2014-07-08	HMM Tijuana Mexico
cPAT Quick Connect Reservoir	CPT-R-274	IIa/3	17605	17605	2014-07-08	HMM Tijuana Mexico
Vacuum Line, Filtered	HAR-A-1000	IIa/2	17605	17605	2014-04-15	HMM Tijuana Mexico

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PRODUCT NAME	REORDER NUMBER OR LIST NO.	DEVICE CLASS /RULE	GMDN	UMDNS	IMPLEMENTATION DATE	FACILITY LOCATION(S)
Vacuum Line, Unfiltered	HAR-A-1001	IIa/2	17605	17605	2014-04-15	HMM Tijuana Mexico
VACUUM LINE, PERI-OP	HAR-A-1002	IIa/2	17605	17605	2014-04-15	HMM Tijuana Mexico
Aspiration & Anticoag Line	HAR-A-1003	IIa/2	17605	17605	2015-04-15	HMM Tijuana Mexico
SmartSuction Harmony Regulator Kit	HAR-EA-1000	IIa/2	17605	17605	2007-03-09	HAE Braintree, MA USA
OPAT advance Integrated Set	OPA-P-1150	IIb/18	17605	17605	2014-07-08	HMM Tijuana Mexico
OPAT Quick Connect Reservoir	OPA-R-1150	IIa/3	17605	17605	2014-07-08	HMM Tijuana Mexico
OPAT QuickConnect Process Set	OPT-P-1000	IIb/18	17605	17605	2014-07-08	HMM Tijuana Mexico
OPAT Quick Connect Reservoir	OPT-R-1000	IIa/3	17605	17605	2014-07-08	HMM Tijuana Mexico
ENVELOPE ASSY,C-SDP,LN 9000,DE ENVELOPE ASSY,C-SDP,LN 9000,FR ENVELOPE ASSY,C-SDP,LN 9000,IT ENVELOPE ASSY,C-SDP,LN 9000,ES ENVELOPE ASSY,C-SDP,LN 9000,SV ENVELOPE ASSY,C-SDP,LN 9000,IE	100770-01 100770-02 100770-03 100770-06 100770-09 100770-30	IIb/11	16405	16405	2005-06-07 2005-07-27 2005-08-04 2005-09-29 2005-08-17 2005-09-29	HAE Braintree, MA USA Sanmina/Tatabánya, Hungary

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PRODUCT NAME	REORDER NUMBER OR LIST NO.	DEVICE CLASS /RULE	GMDN	UMDNS	IMPLEMENTATION DATE	FACILITY LOCATION(S)
ASSY,PROT CARD DIAG,MCS+2 INTL	47536-00	Iib/11	16405	16405	1999-09-08	HAE Braintree, MA USA Sanmina/Tatabánya, Hungary
PACK ASSY, UPP, TECH CONF CARD	112314-00	Iib/11	16405	16405	2012-02-23	HAE Braintree, MA USA Sanmina/Tatabánya, Hungary
ENVELOPE ASSY,UPP,CM,LN9000 ENVELOPE ASSY,UPP,CS,LN9000 ENVELOPE ASSY,UPP,CT,LN9000 ENVELOPE ASSY,UPP,DE,LN9000 ENVELOPE ASSY,UPP,EL,LN9000 ENVELOPE ASSY,UPP,ES,LN9000 ENVELOPE ASSY,UPP,FR,LN9000 ENVELOPE ASSY,UPP,IE,LN9000 ENVELOPE ASSY,UPP,IT,LN9000 ENVELOPE ASSY,UPP,NL,LN9000 ENVELOPE ASSY,UPP,NO,LN9000 ENVELOPE ASSY,UPP,PL,LN9000 ENVELOPE ASSY,UPP,RU,LN9000 ENVELOPE ASSY,UPP,SV,LN9000 ENVELOPE ASSY,UPP,TR,LN9000	112320-CM 112320-CS 112320-CT 112320-DE 112320-EL 112320-ES 112320-FR 112320-IE 112320-IT 112320-NL 112320-NO 112320-PL 112320-RU 112320-SV 112320-TR	Iib/11	16405	16405	2015-02-09 2013-01-28 2015-02-09 2012-02-24 2015-02-09 2012-02-24 2012-04-18 2012-02-24 2012-02-24 2013-08-27 2013-01-28 2013-01-31 2015-02-09 2015-02-09 2013-02-14	HAE Braintree, MA USA Sanmina/Tatabánya, Hungary

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PRODUCT NAME	REORDER NUMBER OR LIST NO.	DEVICE CLASS /RULE	GMDN	UMDNS	IMPLEMENTATION DATE	FACILITY LOCATION(S)
ENVELOPE ASSY,UPP A2,LN9000,CM ENVELOPE ASSY,UPP A2,LN9000,CT ENVELOPE ASSY,UPP A2,LN9000,DE ENVELOPE ASSY,UPP A2,LN9000,ES ENVELOPE ASSY,UPP A2,LN9000,FR ENVEL. ASSY,UPP A2,LN9000,FRFR ENVELOPE ASSY,UPP A2,LN9000,IE ENVELOPE ASSY,UPP A2,LN9000,IT ENVELOPE ASSY,UPP A2,LN9000,KO ENVELOPE ASSY,UPP A2,LN9000,PT ENVELOPE ASSY,UPP A2,LN9000,RO ENV. ASSY,UPP A2,LN9000,RU ENV. ASSY,UPP A2,LN9000,RUBY ENV. ASSY,UPP A2,LN9000,RURU ENVELOPE ASSY,UPP A2,LN9000,TR	118998-CM 118998-CT 118998-DE 118998-ES 118998-FR 118998-FRFR 118998-IE 118998-IT 118998-KO 118998-PT 118998-RO 118998-RU 118998-RUBY 118998-RURU 118998-TR	I Ib/11	16405	16405	2019-06-12 2016-03-29 2016-03-29 2019-06-12 2016-03-29 2016-03-29 2016-03-29 2016-03-29 2020-01-07 2020-01-07 2019-06-12 2021-05-25 2019-06-12 2020-01-07	HAE Braintree, MA USA Sanmina/Tatabánya, Hungary
PACK ASSY,UPP A2,TECH CONF,IE	119003-00	I Ib/11	16405	16405	2016-03-29	HAE Braintree, MA USA Sanmina/Tatabánya, Hungary

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ENVELOPE ASY PPP&FFP DE LN9000 ENVELOPE ASY,PPP&FFP,FR,LN9000 ENVELOP ASSY,PPP&FFP,IT,LN9000 ENVELOP ASSY,PPP&FFP,SP,LN9000 ENVELOPE ASY,PPP&FFP,NL,LN9000 ENVELOP ASSY,PPP&FFP,SW,LN9000 ENVELOPE ASSY,PPP&FFP,NO,LN9000 ENVELOPE ASY,PPP&FFP,IE,LN9000 ENVELOPE ASY,PPP&FFP,RUBY,LN9000	89960-01 89960-02 89960-03 89960-06 89960-08 89960-09 89960-12 89960-30 89960-IEBY	Iib/11	16405	16405	1997-06-09 1998-05-12 1998-12-28 2000-10-12 2000-12-19 1998-12-22 1998-12-22 2003-08-22 2021-05-25	HAE Braintree, MA USA Sanmina/Tatabánya, Hungary
ENVELOPE ASSY,LDP,DE,LN 9000 ENVELOPE ASSY,LDP,FR,LN 9000 ENVELOPE ASSY,LDP,IT,LN 9000 ENVELOPE ASSY,LDP,ES,LN 9000 ENVELOPE ASSY,LDP,PT,LN 9000 ENVELOPE ASSY,LDP,NL,LN 9000 ENVELOPE ASSY,LDP,SV,LN 9000 ENVELOPE ASSY,LDP,NO,LN 9000 ENVELOPE ASSY,LDP,EL,LN9000 ENVELOPE ASSY,LDP,CS,LN 9000 ENVELOPE ASSY,LDP,PL,LN 9000 ENVELOPE ASSY,LDP,TR,LN 9000 ENVELOPE ASSY,LDP,KO,LN 9000 ENVELOPE ASSY, LDP, CM, LN9000	89961-01 89961-02 89961-03 89961-06 89961-07 89961-08 89961-09 89961-12 89961-13 89961-14 89961-17 89961-18 89961-25 89961-26	Iib/11	16405	16405	1997-05-02 1997-04-15 1997-12-08 1998-10-01 2000-09-07 2001-10-08 1998-12-22 1998-12-15 2000-02-29 2003-05-13 2003-05-06 2003-05-06 2004-07-13 2004-07-23	HAE Braintree, MA USA Sanmina/Tatabánya, Hungary

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ENVELOPE ASSY, LDP, CT, LN9000 ENVELOPE ASSY,LDP,IE,LN9000	89961-27 89961-30	Iib/11	16405	16405	2004-07-23 2001-08-31	HAE Braintree, MA USA Sanmina/Tatabánya, Hungary
ENVELOPE ASSY,RBCP+,LN9000,EN ENVELOPE ASSY,RBCP+,LN9000,GE ENVELOPE ASSY,RBCP+,LN9000,FR ENVELOPE ASSY,RBCP+,LN9000,IT ENVELOPE ASSY,RBCP+,LN9000,SW ENVELOPE ASSY,RBCP+,LN9000,NO ENVELOPE ASSY,RBCP+,LN9000,ES	89963-00 89963-01 89963-02 89963-03 89963-09 89963-12 89963-ES	Iib/11	16405	16405	1997-05-07 1997-09-22 2008-06-23 2000-05-18 2000-05-31 2000-05-31 2010-05-10	HAE Braintree, MA USA Sanmina/Tatabánya, Hungary
PBSC PORTFOLIO ENGLISH PBSC PORTFOLIO GERMAN PBCS PORTFOLIO FRENCH PBSC PORTFOLIO ITALY PORTFOLIO PBSC SPANISH	89965-00 89965-01 89965-02 89965-03 89965-06	Iib/11	16405	16405	1997-07-30 1998-01-28 1998-02-05 1998-02-05 1999-03-16	HAE Braintree, MA USA Sanmina/Tatabánya, Hungary
ENVELOPE ASSY,TPE,EN,LN9000 ENVELOPE ASSY,TPE,FR,LN9000 ENVELOPE ASSY,TPE,IT,LN9000 ENVELOPE ASSY,TPE,SP,LN9000 ENVELOPE ASSY,TPE,NO,LN9000	89967-00 89967-02 89967-03 89967-06 89967-12	Iib/11	16405	16405	1999-02-26 2006-09-06 2000-02-09 2008-02-04 2000-12-09	HAE Braintree, MA USA Sanmina/Tatabánya, Hungary

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PRODUCT NAME	REORDER NUMBER OR LIST NO.	DEVICE CLASS /RULE	GMDN	UMDNS	IMPLEMENTATION DATE	FACILITY LOCATION(S)
ENVELOPE ASY,LDPRBC,LN 9000,EN ENVELOPE ASY,LDPRBC,LN 9000,DE ENVELOPE ASY,LDPRBC,LN 9000,FR ENVELOPE ASY,LDPRBC,LN 9000,IT ENVELOPE ASY,LDPRBC,LN 9000,SP ENVELOPE ASY,LDPRBC,LN 9000,NO	89968-00 89968-01 89968-02 89968-03 89968-06 89968-12	IIb/11	16405	16405	1998-07-15 2000-05-11 2004-03-17 2000-01-27 2004-04-29 2000-01-27	HAE Braintree, MA USA Sanmina/Tatabánya, Hungary
ENVELOPE ASY,SDR&TAE LN9000,EN ENVELOPE ASY,SDR&TAE LN9000,GE ENVELOPE ASY,SDR&TAE LN9000,FR ENVELOPE ASY,SDR&TAE LN9000,IT ENVELOPE ASY,SDR&TAE LN9000,SP ENVELOPE ASY,SDR&TAE LN9000,SW ENVELOPE ASY,SDR&TAE LN9000,NO ENVELOPE ASY,SDR&TAE LN9000,GR	89969-00 89969-01 89969-02 89969-03 89969-06 89969-09 89969-12 89969-13	IIb/11	16405	16405	1999-09-06 1999-09-01 1999-06-09 1999-11-08 1999-01-09 1999-11-08 1999-11-08 2000-06-25	HAE Braintree, MA USA Sanmina/Tatabánya, Hungary

DECLARATION OF CONFORMITY - MEDICAL DEVICES

Automated Cell Collection Products (Red Cell, Platelet, Plasma Therapeutics); Blood Management Products (Autologous Cell Salvage, Cell Washing, Suction, Filtering, Rapid Infusion, Freezing & Thawing)

<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 11 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 Corporation 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 019502 0068 Rev. 01 issued by TÜV SÜD Product Service GmbH.</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>