

Declaration of Conformity – DC004

PRODUCT IDENTIFICATION		
Scope of Application	Model/number	GMDN Codes
Canisters for Central Vacuum Systems and Suction	See attached reference list	See attached list

LEGAL MANUFACTURER	
Name of company	Address
Cardinal Health 200, LLC also trading as Cardinal Health	3651 Birchwood Drive Waukegan, IL 60085 USA

EU AUTHORIZED REPRESENTATIVE		
Name of company	Address	Email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	europe@emergogroup.com

REGISTRATION INFORMATION		
Notified Body and ID #	CE certificate number	First Issued (Place/Date)
BSI 2797 Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands	CE 554050	London, October 7, 2009 Traceable to NB 0086

CONFORMITY ASSESSMENT		
Device classification	Route to compliance	Standards applied
Class IIa Rule 11	Annex II.3.2 of MDD 93/42/EEC Council Directive	EN ISO 13485:2016 Medical Devices – Quality Management Systems

Cardinal Health declares that the above-mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices as amended by 2007/47/EC and as transposed in the national laws of the Member States.

MANUFACTURING GROUP MANAGEMENT REPRESENTATIVE: Heather Ferguson

SIGNATURE: 
 Heather Ferguson (Jun 24, 2019) _____ **DATE:** Jun 24, 2019

MEDICAL SEGMENT MANAGEMENT REPRESENTATIVE: Rick Fullenkamp

SIGNATURE: 
 Richard Fullenkamp (Jun 21, 2019) _____ **DATE:** Jun 21, 2019

This schedule is an attachment to Declaration of conformity - DC004

Catalog Number	Specific GMDN Code	Description	1 st Lot Number of CE Marked Products	Lang1	Lang2	Lang3	Lang4	Lang5	Lang6	Lang7	Lang8	Lang9	Lang10	Lang11	Lang12	Lang13	Lang14	Lang15	Lang16	Lang17	Lang18
1-319CE	13846	Cardinal Health™ Medi-Vac™ Guardian™ Suction Canister 1200mL Suction Canister Kit w/6mm 2.7 m tube		English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-120	34858	Cardinal Health™ Medi-Vac™ Guardian™ LVC Suction Canister 12 LiteSuction Canister	J010-203	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-212	34858	Cardinal Health™ Medi-Vac™ Guardian™ Suction Canister 1200ml Suction Canister	J8J097	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-220	34858	Cardinal Health™ Medi-Vac™ Guardian™ Suction Canister 2000ml Suction Canister	J8K106	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-230	34858	Cardinal Health™ Medi-Vac™ Guardian™ Suction Canister 3000ml Guardian Suction Canister	J8J096	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-312	34858	Cardinal Health™ Medi-Vac™ Guardian™ Suction Canister 1200 mL Suction Canister Kit with 5 mm 1.8 m Tube	J8J637	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-320	34858	Cardinal Health™ Medi-Vac™ Guardian™ Suction Canister 2000 mL Suction Canister Kit with 5 mm 1.8 m Tube	J8J642	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-412	34858	Cardinal Health™ Medi-Vac™ Guardian™ PPV Suction Canister 1200ml PPV Suction Canister	J306-068	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-420	34858	Cardinal Health™ Medi-Vac™ Guardian™ PPV Suction Canister 2000ml PPV Suction Canister	J306-070	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-430	34858	Cardinal Health™ Medi-Vac™ Guardian™ PPV Suction Canister 3000ml PPV Suction Canister	J306-071	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-510	44942	Cardinal Health™ Medi-Vac™ CRD™ Suction Canister Liner 1000 mL Thin Wall Suction Canister Liner	J8E026	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-515	44942	Cardinal Health™ Medi-Vac™ CRD™ Suction Canister Liner 1500 mL Thin Wall Suction Canister Liner	J8E047	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-517	44942	Cardinal Health™ Medi-Vac™ CRD™ Suction Canister Liner 1000 mL Suction Canister Liner Kit with 6 mm 1.8 m Tube		English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-527	44942	Cardinal Health™ Medi-Vac™ CRD™ Suction Canister Liner 1500 mL Suction Canister Liner Kit with 6 mm 1.8 m Tube		English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-530	44942	Cardinal Health™ Medi-Vac™ CRD™ Suction Canister Liner	J8E038	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-539	44942	Cardinal Health™ Medi-Vac™ CRD™ Suction Canister Liner 3000 mL Suction Canister Liner Kit with 6 mm 2.7 m Tube		English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651910	44942	Cardinal Health™ Medi-Vac™ CRD™ Flex Advantage™ Liners	98F082100	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-910C	44942	Cardinal Health™ Medi-Vac™ Flex Advantage™ Liners 1000 mL	J3S225	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-910P	44942	Cardinal Health™ Medi-Vac™ CRD™ Flex Advantage™ Liners 1000 mL		English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651910PG	44942	Cardinal Health™ Medi-Vac™ CRD™ Flex Advantage™ Liners 1000 mL + Gel Vac	05A062010	English	French	German	Italian	Spanish	Dutch												
65651916	13846	Cardinal Health™ Medi-Vac™ Flex Advantage™ Liners 1000 mL	98F082160	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-916K	42988	Cardinal Health™ Medi-Vac™ Flex Advantage™ Suction Canister Liner – 1000 mL Liner Kit with 6 mm 1.8 m Tube	J4D403	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-919K	42988	Cardinal Health™ Medi-Vac™ Flex Advantage™ Suction Canister Liner - 1000 mL Liner Kit with 6 mm 2.7 m Tube	J8N458	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651920	44942	Cardinal Health™ Medi-Vac™ CRD™ Flex Advantage™ Liner 1500 mL	98E15203	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-920C	44942	Cardinal Health™ Medi-Vac™ Flex Advantage™ Suction Canister Liner 1500ml	J3N257	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-920P	44942	Cardinal Health™ Medi-Vac™ CRD™ Flex Advantage™ Liners 1500ml	13F77	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651920PG	44942	Cardinal Health™ Medi-Vac™ Flex Advantage™ + Gel-Vac 1500ml	05A09Z020	English	French	German	Italian	Spanish	Dutch												
65651926	13846	Cardinal Health™ Medi-Vac™ CRD™ Flex Advantage 1500ml	98E19Z263	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-926K	13846	Cardinal Health™ Medi-Vac™ Flex Advantage™ Suction Canister Liner 1500 mL Liner Kit with 6 mm 1.8 m Tube	J8N401	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651929	13846	Cardinal Health™ Medi-Vac™ CRD™ Flex Advantage Liners with 2.7m tube	98E22Z290	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-929K	13846	Cardinal Health™ Medi-Vac™ Flex Advantage™ Suction Canister –1500 mL Liner Kit with 6 mm 2.7 m Tube	J8P406	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651930	44942	Cardinal Health™ Medi-Vac™ Flex Advantage™ Liner 3000 mL	98E25Z300	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-930C	44942	Cardinal Health™ Medi-Vac™ Flex Advantage™ Suction Canister Liner 3000ml	J3B259	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-930P	44942	Cardinal Health™ Medi-Vac™ CRD™ Flex Advantage™ 3000ml	13F88	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651930GT	13846	Cardinal Health™ Medi-Vac™ Flex Advantage™ + Gel-Vac 3000ml + Tandem Tube		English	French	German	Italian	Spanish	Dutch												
65651930PG	44942	Cardinal Health™ Medi-Vac™ Flex Advantage™ + Gel-Vac 3000ml	05A20Z030	English	French	German	Italian	Spanish	Dutch												
65651936	13846	Cardinal Health™ Medi-Vac™ Flex Advantage™ Liner Kit with 1.8 m tube	98F05Z360	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-936K	13846	Cardinal Health™ Medi-Vac™ Flex Advantage™ Suction Canister 3000 mL Liner Kit with 6 mm 1.8 m Tube	J9A421	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651939	13846	Cardinal Health™ Medi-Vac™ Flex Advantage™ Liners with 2.7 m tube	98E25Z390	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65652-002	16779	Cardinal Health™ Medi-Vac™ Two Canister Manifold	227114	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65652-002A	16779	Cardinal Health™ Medi-Vac™ Two Canister Manifold		English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65652-003	16779	Cardinal Health™ Medi-Vac™ Three Canister Manifold	232195	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65652-003A	16779	Cardinal Health™ Medi-Vac™ Three Canister Manifold		English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65652-004	16779	Cardinal Health™ Medi-Vac™ Four Canister Manifold	227446	English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian

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65651-319	13846	Cardinal Health™ Medi-Vac™ Guardian™ Suction Canister 6mm x 2.7m tubing		English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-395	13846	Medivac Guardian Canister plus 5mm x 1.8m tubing		English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-516	13846	Medivac Guardian Canister plus 5mm x 1.8m tubing		English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-526	13846	Medivac Guardian Canister plus 5mm x 1.8m tubing		English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-529	13846	Medivac Guardian Canister plus 6mm x 2.7m tubing		English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-896	13846	Cardinal Health™ Medi-Vac™ Guardian™ Suction Canister 1200 mL Suction Canister Kit with 6 mm 1.8 m Tube		English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-910M	44942	Cardinal Health™ Medi-Vac™ Flex Advantage™ Liner 1000 mL		English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-920M	44942	Cardinal Health™ Medi-Vac™ Flex Advantage™ Liner 1500mL		English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65651-930M	44942	Cardinal Health™ Medi-Vac™ Flex Advantage™ Liner 3000mL		English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65652-620	16779	Cardinal Health™ Medi-Vac™ Flex Advantage™ Tandem Tube		English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
6565-910PG	44942	Cardinal Health™ Medi-Vac™ Flex Advantage™ + Gel-Vac 1000mL		English	French	German	Italian	Spanish	Dutch												
6565-920PG	44942	Cardinal Health™ Medi-Vac™ Flex Advantage™ + Gel-Vac 1500ml		English	French	German	Italian	Spanish	Dutch												
6565-930PG	44942	Cardinal Health™ Medi-Vac™ Flex Advantage™ + Gel-Vac 3000ml		English	French	German	Italian	Spanish	Dutch												
65653916A	44942	Cardinal Health™ Medi-Vac™ CRD Flex Advantage 1000ml		English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65653926A	44942	Cardinal Health™ Medi-Vac™ CRD Flex Advantage 1500ml		English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
65653929	44942	Cardinal Health™ Medi-Vac™ Flex Advantage 1500ml		English	French	German	Spanish	Italian	Portuguese	Dutch	Swedish	Norwegian	Greek	Czech	Slovene	Finnish	Icelandic	Turkish	Polish	Danish	Romanian
656-910PPG	44942	Cardinal Health™ Medi-Vac™ Flexible Liner with PPV + Gel-Vac 1000ml		English	French	German	Spanish	Italian	Dutch	Romanian	Polish										
656-920PPG	44942	Cardinal Health™ Medi-Vac™ Flexible Liner with PPV + Gel-Vac 1500ml		English	French	German	Spanish	Italian	Dutch	Romanian	Polish										
656-930PPG	44942	Cardinal Health™ Medi-Vac™ Flexible Liner with PPV + Gel-Vac 3000ml		English	French	German	Spanish	Italian	Dutch	Romanian	Polish										

GMDN Table	
Code	Description
34858	Suction system canister, single use
44942	Suction system canister liner
42988	Tubing connector
42446	Holder, suction unit, canister/bottle
44943	Suction system canister, reusable
44035	Container, adaptor
16779	Suction system tubing
35375	Stopcock
13846	Secretion Suction Kit

Change History

Date	Description
1/23/2016	Issue new document format
2/6/2017	Updated Catalog List page Verified Languages Updated Emergo address
7/14/2017	Updated the Legal Manufacturer Address Added new product codes to the DOC (85651-319, 85651-395, 85651-516, 85651-526, 85651-529 & 85651-896) Added Romanian Language
8/7/2017	Added new product codes to the DOC (65651-910M, 65651-920M, 65651-930M, 65652-620, 6565-910PG, 6565-920PG, 6565-930PG, 65653916, 65653926 & 65653929)
12/21/2017	GMDN code correction was made to the following catalog numbers: 65652-513, 65652-518, 65652-533, 65652-613 and 65652-618
1/29/2019	Removed product codes 65652-107, 65652-119, 65652-120, and 65652-109 and moved them to the Class I DOC-DC044 Added product codes 656-910PPG, 656-920PPG and 656-930PPG
2/20/2019	Updated Legal Manufacturer Address and ISO 13485 revision date
6/18/2019	Updated NB number and address addition of Arvato codes, 65652-159A, 65652-580A, 65652-611A, 65652-613A, 65652-616A, 65652-631A, 65652-633A, 65652-914A 65652-915A, 65652-916A, 65652-002A, 65652-003A, 65652-004A, 65652-163A, 65652-550A, 65652-516A, 65652-511A, 65652-580A, 65652-551A Updated product description to match device labeling