FLOW METER S.p.A.
Capitale Sociale: € 234.000 int. versato
Sede legale Via del Lino, 6 - 24040 LEVATE (Bg)
Amministrazione e Stabilimenti: Via del Lino, 6 - 24040 LEVATE (Bg)
Tel. +39/035/594047 - Telefax +39/035/594821
http://www.flowmeter.it - email info@flowmeter.it
Codice fiscale e Partita IVA: 01737040160 -
C.C.I.A.A. Bergamo 233737
Iscritta al Tribunale di Bergamo -
Volume 29771 - Reg. Società 30722

UNI EN ISO 9001:2015
UNI CEI EN ISO 13485:2016

DECLARATION OF CONFORMITY FOR THE MEDICAL DEVICE FAMILY "COLLECTION CONTAINERS FOR SUCTION LIQUIDS" FLOVAC series IDENTIFIED WITH BASIC UDI-DI 805729821A06991MDT21XK

whose codes are specified in the attachment, to the General Safety and Performance Requirements referred to in Annex I of the EU Regulation 2017/745 on medical devices and subsequent amendments and corrections.

FLOW METER S.p.A., with registered office and operation site in Via del Lino, 6, zip code 24040 - Levate (BG) - I, manufacturer of the medical devices named "**COLLECTION CONTAINERS FOR SUCTION LIQUIDS**", codes are reported in the attachment,

declares under its own responsibility that the devices in question satisfy all the General Safety and Performance Requirements required by Annex I of the EU Regulation 2017/745.

For this purpose it hereby guarantees and declares under its own responsibility that:

1. The devices in question satisfy the dispositions applicable under the EU Regulation 2017/745, as required by the procedure of Article 52 "Conformity assessment procedures", point 7 of the aforementioned Regulation.
2. The devices in question should be considered as belonging to class I with measuring function according to Rule 1 of Annex VIII of the EU Regulation 2017/745.
3. The devices in question are sold in NON-STERILE packaging and that for the devices having a measuring function, the traceability to the metrological reference is assured thanks to the calibration of the control instruments and their reference to primary qualified samples and to recognized primary standards.
4. The design and manufacturing process is conducted in compliance with the requirements of the company's Quality Management System, in accordance with the requirements of Annex IX of the EU Regulation 2017/745.
5. FLOW METER S.p.A. undertakes to preserve and keep available to the Competent Authority the product Technical Documentation, specified in Annexes II and III of the EU Regulation 2017/745, for a period of at least ten years from the last date of placing on the market of the last batch of the product.
6. The a.m. medical devices comply with all the requirements of the following standards:

– EN ISO 10079-1 "Medical suction equipment -- Part 1: Electrically powered suction equipment"
– EN ISO 10079-3 "Medical suction equipment - Part 3: Suction equipment powered from a vacuum or pressure source"

7. The devices in question have been designed, manufactured and placed on the market as indicated in the Product Technical Documentation and according to the company Quality System declared to be compliant by Kiwa Cermet Italia S.p.A, Notified Body number 0476 according to EU Regulation 2017/745, as prescribed in annex IX, chapter I and III - Conformity assessment based on a quality management system and on assessment of technical documentation of the EU Regulation 2017/745 (certificate no. MDR 00006-C, first issue of 03.06.2022, and valid up to 02.06.2027, referred in Attachment 2). This system, adopted for the design and manufacturing of all devices, is declared as conforming to standards ISO 9001 and EN ISO 13485, current edition (ref. certificate no.19026 – A and certificate no. 19026 – M issued by KIWA Cermet Italia S.p.A. – Via Cadriano, 23 – 40057 Granarolo dell'Emilia (BO) - Italy).
8. FLOW METER S.p.A. has already notified the Italian Competent Authority of the placing on the market of the aforementioned devices. It also declares to have established and to maintain an appropriate procedure to ensure the post-marketing surveillance measures required by the EU Regulation 2017/745 on medical devices.

The content of this declaration of conformity, issued under the sole responsibility of the manufacturer FLOW METER S.p.A., is confirmed at each code release and at each batch release of the indicated devices, produced starting since 03/06/2022.

Attachments: List of models with codes to which this declaration refers and FLOVAC devices accessories.
Copy of the CE marking certificate.

Witnessed
Flow Meter S.p.A.
The legal representative
Roberto Paratico

Date of issue of the declaration: 03/06/2022 - Ed. / Is.: 01/0

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Attachment 01 – List of models – Updated 03/06/2022

Model	Code	Volume	Patient Tubing	Vacuum Breaker	Use with Liner	RDM identifier	CND classification and European Nomenclature
Canister Flovac 0,5 L.	000036106	500 ml				2268522	A0699
Canister Flovac 1.0 L.	000036000	1000 ml					
Canister Flovac 2.0 L.	000036001	2000 ml					
Canister Flovac 3.0 L.	000036002	3000 ml					
Canister Flovac 1.0 L. with mechanical valve	000036065	1000 ml					
Canister Flovac 2.0 L. with mechanical valve	000036066	2000 ml					
Canister Flovac 3.0 L. with mechanical valve	000036067	3000 ml					
Liner Flovac 1.0 L.	000036010	1000 ml				2268518	A0699
Liner Flovac 1.5 L.	000036014	1500 ml					
Liner Flovac 2.0 L.	000036011	2000 ml					
Liner Flovac 3.0 L.	000036012	3000 ml					
Liner Flovac 1.0 L. EXCLUSIVE	000036013	1000 ml					
Liner Flovac 1.0 L with mechanical valve	000036060	1000 ml					
Liner Flovac 1.5 L with mechanical valve	000036063	1500 ml					
Liner Flovac 2.0 L with mechanical valve	000036061	2000 ml					
Liner Flovac 3.0 L with mechanical valve	000036062	3000 ml					
Liner FLOVAC 1,0 L Anti-reflux Valve	000036007	1000 ml					
Liner FLOVAC 2,0 L Anti-reflux Valve	000036008	2000 ml					
Liner FLOVAC 3,0 L Anti-reflux Valve	000036009	3000 ml					
Liner FLOVAC 1,0 L mechanical and Anti-reflux Valve	000036071	1000 ml					
Liner FLOVAC 2,0 L mechanical and Anti-reflux Valve	000036072	2000 ml					
Liner FLOVAC 3,0 L mechanical and Anti-reflux Valve	000036073	3000 ml					

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Model	Code	Volume	Patient Tubing	Vacuum Breaker	Use with Liner	RDM identifier	CND classification and European Nomenclature
Liner FLOVAC 1,0 L mechanical and Anti-reflux Valve with Tubing L = 1,8 m	000036075	1000 ml	Ø6.0X9.0 mm L=1.8 m			2268518	A0699
Liner Flovac 1.0 L. with gelling kit	000036015	1000 ml					
Liner Flovac 1.5 L. with gelling kit	000036018	1500 ml					
Liner Flovac 2.0 L. with gelling kit	000036016	2000 ml					
Liner Flovac 3.0 L. with gelling kit	000036017	3000 ml					
Liner Flovac 1.0 L. with gelling kit with mechanical valve	000036068	1000 ml				2268524	A0699
Liner Flovac 1.5 L. with gelling kit with mechanical valve	000036074	1500 ml					
Liner Flovac 2.0 L. with gelling kit with mechanical valve	000036069	2000 ml					
Liner Flovac 3.0 L. with gelling kit with mechanical valve	000036070	3000 ml					
Reusable Flovac Canister 1.0 L.	970010211	1000 ml					
Reusable Flovac Canister 1.5 L.	970010327	1500 ml					
Reusable Flovac Canister 2.0 L.	970010212	2000 ml					
Reusable Flovac Canister 3.0 L.	970010213	3000 ml				2268541	A0699
Reusable Flovac Canister 1.0 L. EXCLUSIVE	970010245	1000 ml					
Reusable Flovac Canister 1.0 L. blue	970010289	1000 ml					
Reusable Flovac Canister 2.0 L. blue	970010290	2000 ml					

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Model	Code	Volume	Patient Tubing	Vacuum Breaker	Use with Liner	RDM identifier	CND classification and European Nomenclature
Canister Flovac 1.0 L. with Tubing L = 1,8 m	000036020	1000 ml	Ø6.0X9.0 mm L=1.8 m			2268522	A0699
Canister Flovac 2.0 L. with Tubing L = 1,8 m	000036021	2000 ml	Ø6.0X9.0 mm L=1.8 m				
Canister Flovac 3.0 L. with Tubing L = 1,8 m	000036022	3000 ml	Ø6.0X9.0 mm L=1.8 m				
Liner Flovac 1.0 L. with Tubing L = 1,8 m	000036030	1000 ml	Ø6.0X9.0 mm L=1.8 m			2268526	A0699
Liner Flovac 2.0 L. with Tubing L = 1,8 m	000036031	2000 ml	Ø6.0X9.0 mm L=1.8 m				
Liner Flovac 3.0 L. with Tubing L = 1,8 m	000036032	3000 ml	Ø6.0X9.0 mm L=1.8 m				
Canister Flovac 1.0 L. with Tubing L = 1,8 m and vacuum breaker	000036040	1000 ml	Ø6.0X9.0 mm L=1.8 m			2268522	A0699
Canister Flovac 2.0 L. with Tubing L = 1,8 m and vacuum breaker	000036041	2000 ml	Ø6.0X9.0 mm L=1.8 m				
Canister Flovac 3.0 L. with Tubing L = 1,8 m and vacuum breaker	000036042	3000 ml	Ø6.0X9.0 mm L=1.8 m				
Liner Flovac 1.0 L. with Tubing L = 1,8 m and vacuum breaker	000036050	1000 ml	Ø6.0X9.0 mm L=1.8 m			2268528	A0699
Liner Flovac 2.0 L. with Tubing L = 1,8 m and vacuum breaker	000036051	2000 ml	Ø6.0X9.0 mm L=1.8 m				
Liner Flovac 3.0 L. with Tubing L = 1,8 m and vacuum breaker	000036052	3000 ml	Ø6.0X9.0 mm L=1.8 m				

AVAILABLE NOT AVAILABLE