

**DECLARATION OF CONFORMITY FOR THE MEDICAL DEVICE FAMILY
“ACCESSORIES FOR COLLECTION CONTAINERS FOR SUCTION LIQUIDS – FLOVAC SERIES”
IDENTIFIED WITH BASIC UDI-DI 805728921A06800000U9**

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.

The undersigned FLOW METER S.p.A., SRN IT-MF-000029985, with registered office and operation site in Via del Lino, 6, zip code 24040 - Levate (BG) - I, manufacturer of the medical devices named “ACCESSORIES FOR COLLECTION CONTAINERS FOR SUCTION LIQUIDS – FLOVAC SERIES”, whose 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:

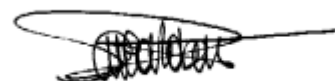
1. The devices in question satisfy the dispositions applicable under the EU Regulation 2017/745, as required by the procedure of Article 52 “Conformity assessment procedures”, point 7 of the aforementioned Regulation.
2. The devices in question should be considered as belonging to class I according to Rule 1 of Annex VIII of the EU Regulation 2017/745.
3. The devices in question are put on the market in NON STERILE packaging.
4. The above-mentioned devices are manufactured in different versions as stated in the list of product codes in the attachment.
5. 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.
6. 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.
7. The devices comply with the state-of-the-art requirements referred to in the standards mentioned in the current edition of the Technical Documentation.
8. The devices are designed, manufactured and marketed as stated in the product Technical Documentation.
9. The company's Quality Management System complies with UNI EN ISO 9001 and UNI CEI EN ISO 13485 standards, 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).
10. 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 17/01/2024.

This declaration is valid for a maximum of five years from the date of issue.

Attachments: List of models with codes to which this declaration refers.

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



Date of issue of the declaration: 17/01/2024 - Ed. / Is.: 01/3

Attachment 01 – List of models – Updated 17/01/2024

Codice FM	Modello	Identificativo RDM	Classificazione CND e Nomenclatore Europeo
000010057	On-off tap for mounting on Flovac container support ring	2269966	A0680
000260945	4-place trolley for Flovac with ON – OFF and rings	2269967	A0699
000260952	Trolley for Flovac Taema		
000260953	4-place trolley for Flovac with handle and rings		
000260954	2-place trolley for Flovac with handle and rings		
000260963	Trolley for regulator lagoon with 3 rings for Flovac with plate 30x5		
000260969	Four-place trolley with smaller base for Flovac with handle and rings		
000250021	Vacuum trolley Easy with handle		
970010214	Support ring for Flovac container with 41x4 slide	2269968	A0680
970010215	Support ring for Flovac container with 45x5 slide		
970010210	Support ring for Flovac container with 25x5 slide		
970010220	Support ring for Flovac container with 30x5 slide		
970010120	Tubing \varnothing 7,5x11,2 mm l=0.38 m for Tandem connection (50 pieces pack)	2269969	A0699
930070174	Tubing \varnothing 7,5x11,2 mm L=1.80 m (100 pieces pack)	2269972	A0680
920200004	25x5 wall slide in technopolymer		
920200029	30x5 wall slide in technopolymer		
920200477	45x5 wall slide in technopolymer	2269973	A0680
000230000	Rail clamping bracket for 30x10 rail in chromed metal with 25x5 slide		
000230500	Rail clamping bracket 30x10 rail in ABS with 25x5 slide		
000230510	Rail clamping bracket 30x10 rail in ABS with 30x5 slide	2264455	A06030499
000320000	Single use Vacuum-stop lancet (50 pieces pack)		
000320010	Tubing \varnothing 7,5x11,2 mm L=1.80 m complete with single use Vacuum-stop lancet (100 pieces pack)	2269962	A06030499
000036100	Specimen container (10 pieces pack)	2269974	A0699
000036101	Tubing \varnothing 7.5x11.2 mm L=0.38 m, complete with reusable Vacuum supply connection for Flovac canisters (50 pieces pack)	2269969	A0699
000036103	Tandem connection	2269975	A0699
000036150	Gelling kit for Flovac 1.0 L, 2.0 L and 3.0 L Canister (50 pieces pack)		
000036151	Gelling kit for Canister Flovac 3.0 L		
000036149	Gelling kit for single use Flovac canisters		

Codice FM	Modello	Identificativo RDM	Classificazione CND e Nomenclatore Europeo
000036102	Reusable Vacuum supply connection for Flovac canisters (25 pieces pack)	2269974	A0699
000036104	Tubing Ø 7,5x11,2 mm L=0,38 m with angled male connector for Flovac		
000036105	Vacuum male angled connector in PC for Flovac		
000250100	Trolley for Monokit connected vessels	2269976	A0680
000260900	Double little trolley for jar MAK/2000		
000260902	Double little trolley for jar MAK/4000		