

CERTIFICATE OF CONFORMITY

MEDICA S.p.A., with offices at: via degli Artigiani, 7 - 41036 Medolla (MO) - ITALY, declares that the products listed below:

CODE	DESCRIPTION	SAMPLE BATCH	STERILIZATION		PIECES	CONTROLLED ENVIRONMENT	EC
			FACILITY	BATCH and DATE			
93024-124	HPH-1000TS HEMOCONCENTRATOR	PI26/0245	STERILVERONA	STERILE - 260323A64 4 gg degas of 28 March 2026	100	UNI EN ISO 14644 - ISO class 8	MDR 00048
93024-121	HPH-1000 HEMOCONCENTRATOR	PI26/0279	STERILVERONA	STERILE - 260328A64 4 gg degas of 3 April 2026	1008	UNI EN ISO 14644 - ISO class 8	MDR 00048
93024-256M	PF HPH JUNIOR	PM26/0058	STERILVERONA	STERILE - 260328A64 4 gg degas of 3 April 2026	432	UNI EN ISO 14644 - ISO class 8	NA
M03960B	DP 12 HC Hemoconcentrator Emoconcentratore DP 12 HC	PI26/0263	STERILVERONA	STERILE - 260323A64 4 gg degas of 28 March 2026	396	UNI EN ISO 14644 - ISO class 8	NA
M03959B	DP 09 HC Hemoconcentrator Emoconcentratore DP 09 HC	PI26/0255	STERILVERONA	STERILE - 260323A64 4 gg degas of 28 March 2026	1440	UNI EN ISO 14644 - ISO class 8	NA
93024-256M	PF HPH JUNIOR	PM26/0059	STERILVERONA	STERILE - 260328A64 4 gg degas of 3 April 2026	808	UNI EN ISO 14644 - ISO class 8	NA
M03957B	DP 03 HC Hemoconcentrator Emoconcentratore DP 03 HC	PI26/0254	STERILVERONA	STERILE - 260323A64 4 gg degas of 28 March 2026	590	UNI EN ISO 14644 - ISO class 8	NA
M03958B	DP 07 HC Hemoconcentrator Emoconcentratore DP 07 HC	PI26/0291	STERILVERONA	STERILE - 260328A64 4 gg degas of 3 April 2026	1344	UNI EN ISO 14644 - ISO class 8	NA
M03959B	DP 09 HC Hemoconcentrator Emoconcentratore DP 09 HC	PI26/0310	STERILVERONA	STERILE - 260403A64 4 gg degas of 8 April 2026	1440	UNI EN ISO 14644 - ISO class 8	NA
M68797	Ghiera x D050	SB25/6261	NA	NOT STERILE	2000	UNI EN ISO 14644 - ISO class 8	NA

- have been manufactured under technic, quality (products/processes) and regulatory (product/system) requirements of Medica S.p.A.

and are conforming to the requirements mentioned below :

POST-STERILIZATION VERIFICATIONS

BATCH	PROCESS and FACILITY	CERTIFICATE	RESULT
PI26/0245	ETHYLENE OXIDE - Steril Verona s.r.l. - via del Lavoro, 25 - 37060 Trevenzuolo (VR) - ITALY	Sterilization Records - Document: 260323A64 BI's Inspection - COMPLIANT on date 01 April 2026	4 gg degas COMPLIANT COMPLIANT
PI26/0279	ETHYLENE OXIDE - Steril Verona s.r.l. - via del Lavoro, 25 - 37060 Trevenzuolo (VR) - ITALY	Sterilization Records - Document: 260328A64 BI's Inspection - COMPLIANT on date 09 April 2026	4 gg degas COMPLIANT COMPLIANT

PM26/0058	ETHYLENE OXIDE - Steril Verona s.r.l. - via del Lavoro, 25 - 37060 Trevenzuolo (VR) – ITALY	Sterilization Records - Document: 260328A64 BI's Inspection - COMPLIANT on date 09 April 2026	4 gg degas	COMPLIANT COMPLIANT
PI26/0263	ETHYLENE OXIDE - Steril Verona s.r.l. - via del Lavoro, 25 - 37060 Trevenzuolo (VR) – ITALY	Sterilization Records - Document: 260323A64 BI's Inspection - COMPLIANT on date 01 April 2026	4 gg degas	COMPLIANT COMPLIANT
PI26/0255	ETHYLENE OXIDE - Steril Verona s.r.l. - via del Lavoro, 25 - 37060 Trevenzuolo (VR) – ITALY	Sterilization Records - Document: 260323A64 BI's Inspection - COMPLIANT on date 01 April 2026	4 gg degas	COMPLIANT COMPLIANT
PM26/0059	ETHYLENE OXIDE - Steril Verona s.r.l. - via del Lavoro, 25 - 37060 Trevenzuolo (VR) – ITALY	Sterilization Records - Document: 260328A64 BI's Inspection - COMPLIANT on date 09 April 2026	4 gg degas	COMPLIANT COMPLIANT
PI26/0254	ETHYLENE OXIDE - Steril Verona s.r.l. - via del Lavoro, 25 - 37060 Trevenzuolo (VR) – ITALY	Sterilization Records - Document: 260323A64 BI's Inspection - COMPLIANT on date 01 April 2026	4 gg degas	COMPLIANT COMPLIANT
PI26/0291	ETHYLENE OXIDE - Steril Verona s.r.l. - via del Lavoro, 25 - 37060 Trevenzuolo (VR) – ITALY	Sterilization Records - Document: 260328A64 BI's Inspection - COMPLIANT on date 09 April 2026	4 gg degas	COMPLIANT COMPLIANT
PI26/0310	ETHYLENE OXIDE - Steril Verona s.r.l. - via del Lavoro, 25 - 37060 Trevenzuolo (VR) – ITALY	Sterilization Records - Document: 260403A64 BI's Inspection - COMPLIANT on date 10 April 2026	4 gg degas	COMPLIANT COMPLIANT
SB25/6261	NA	NA		

Medolla (MO) 20 April 2026

Notes:

Document: FTE 1021-2026

For each code in this certificate, the validity of the current CE certificate (if applicable) has been verified and the presence of any sales restrictions by the notified body has been excluded.

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