

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			
M03960B	DP 12 HC Hemoconcentrator Emoconcentratore DP 12 HC	PI25/0827	STERILVERONA	STERILE - 251020A64 4 gg degas of 25 October 2025	78	UNI EN ISO 14644 - ISO class 8	NA
M03960B	DP 12 HC Hemoconcentrator Emoconcentratore DP 12 HC	PI26/0225	STERILVERONA	STERILE - 260317A64 4 gg degas of 22 March 2026	882	UNI EN ISO 14644 - ISO class 8	NA
93024-121	HPH-1000 HEMOCONCENTRATOR	PI26/0134	STERILVERONA	STERILE - 260223A64 4 gg degas of 28 February 2026	1008	UNI EN ISO 14644 - ISO class 8	MDR 00048
93024-121M	PF HPH 1000 HEMOCONCENTRATOR FDA	PI26/0216	STERILVERONA	STERILE - 260317A64 4 gg degas of 22 March 2026	948	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
PI25/0827	ETHYLENE OXIDE - Steril Verona s.r.l. - via del Lavoro, 25 - 37060 Trevenzuolo (VR) – ITALY	Sterilization Records - Document: 251020A64 BI's Inspection - COMPLIANT on date 29 October 2025	4 gg degas COMPLIANT COMPLIANT
PI26/0225	ETHYLENE OXIDE - Steril Verona s.r.l. - via del Lavoro, 25 - 37060 Trevenzuolo (VR) – ITALY	Sterilization Records - Document: 260317A64 BI's Inspection - COMPLIANT on date 25 March 2026	4 gg degas COMPLIANT COMPLIANT
PI26/0134	ETHYLENE OXIDE - Steril Verona s.r.l. - via del Lavoro, 25 - 37060 Trevenzuolo (VR) – ITALY	Sterilization Records - Document: 260223A64 BI's Inspection - COMPLIANT on date 04 March 2026	4 gg degas COMPLIANT COMPLIANT
PI26/0216	ETHYLENE OXIDE - Steril Verona s.r.l. - via del Lavoro, 25 - 37060 Trevenzuolo (VR) – ITALY	Sterilization Records - Document: 260317A64 BI's Inspection - COMPLIANT on date 25 March 2026	4 gg degas COMPLIANT COMPLIANT

Medolla (MO) 20 April 2026

Notes:

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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