

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 | 660 | UNI EN ISO 14644 - ISO class 8 | MDR 00048 |
| 93024-124 | HPH-1000TS HEMOCONCENTRATOR | PI26/0299 | STERILVERONA | STERILE - 260328A64 4 gg degas of 3 April 2026 | 240 | UNI EN ISO 14644 - ISO class 8 | MDR 00048 |
| 93024-118 | HPH-700TS HEMOCONCENTRAT | PI25/0384 | STERILVERONA | STERILE - 250611A64 4 gg degas of 16 June 2025 | 60 | UNI EN ISO 14644 - ISO class 8 | MDR 00048 |
| 93024-118 | HPH-700TS HEMOCONCENTRAT | PI26/0302 | STERILVERONA | STERILE - 260403A64 4 gg degas of 8 April 2026 | 1600 | UNI EN ISO 14644 - ISO class 8 | MDR 00048 |

- 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 |
| PI26/0299 | 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 |
| PI25/0384 | ETHYLENE OXIDE - Steril Verona s.r.l. - via del Lavoro, 25 - 37060 Trevenzuolo (VR) – ITALY | Sterilization Records - Document: 250611A64 BI's Inspection - COMPLIANT on date 19 June 2025 | 4 gg degas COMPLIANT COMPLIANT |
| PI26/0302 | 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 |

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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