

Press Release

MEDICA S.P.A.
**510k authorization from the US FDA for the distribution of
hemoconcentrators on the US market**

Medolla (MO), 8 February 2024 – Medica S.p.A., an integrated Italian biomedical and MedTech group with a strong international footprint, announces with great satisfaction that it has received the 510k distribution authorization from the US FDA through its subsidiary Tecnoideal America Inc of hemoconcentrators, produced by Medica, on the US market, with the indication of use on adult patients for the removal of excess fluids from the blood for the purpose of restoring physiological blood conditions during or at the end of cardiopulmonary bypass surgery.

President Luciano Fecondini comments: "the FDA approval of 510k for the distribution of hemoconcentrators opens important commercial opportunities for Medica in the largest worldwide market. Hemoconcentrators represent only the first class of approved devices; the application for FDA approval has already started for a series of other devices in Medica's product portfolio."

Medica Profile

Medica Group is operating since 1985 in the biomedical district of Mirandola (Italy). Development of innovative products for blood purification has always been company's core business. Thanks to the activity of two extremely dynamic R&D groups (medical equipment, membranes and disposable), the Group competes successfully in several markets, namely:

- **Medical** (dialysis, CRRT, ECCO2, Apheresis, DFPP, CHF, HIPEC, pre-transplant organ perfusion, bioregenerative medicine, gastroenterology, urodynamics, oxygen humidification).
- **Microbiological purification of water**
- **Industrial automation** for the biomedical sector.

R&D focus has been integrated over the years with a highly automated production systems in several facilities, and with different commercial entities, both in Italy and abroad.

The key success factors of the Group are:

- **extrusion of hollow fiber membranes** for hemofiltration, plasmapheresis, cascade filtration, oxygen humidification, ultrafiltration and microfiltration of water
- **vertical integration**, proved by the ability to manage not only the design and development of medical disposables and equipment, and the development of the automation technologies required for their production as well.
- **International recognition with significant share of export**, with sales in over 60 countries.

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

Capitale sociale € 4.223.250,00 i.v. – Registro Ditte/REA n° 229672 – Registro Imprese di Modena n° 01604300366
Iscrizione Registro Nazionale Produttori A.E.E. n. IT08020000003645
Partita IVA e Codice Fiscale 01604300366 – Identification Number IT 01604300366

The Medica group closed its consolidated financial statements for 2022 with revenues of 50.9 million euros (43.8 million euros in 2021), EBITDA of 11.2 million euros (9.9 million euros in 2021), EBIT of € 5.3 million (€ 5.8 million in 2021) and net profit of € 4.0 million (€ 5.0 million in 2021).

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