

WISE SpA first to achieve MDR certification of cortical strip for Neuromonitoring

The WISE Cortical Strip (WCS®) is the first cortical strip for Intraoperative Neurophysiological Monitoring (IONM) to achieve CE mark under MDR (1)

MILAN, ITALY, July 11, 2025

/EINPresswire.com/ -- WISE SpA, a pioneering medical device company specialising in advanced implantable electrodes for neuromonitoring, neuromodulation and brain-machine interfacing (BMI), today announced that its WISE Cortical Strip (WCS®) is the first cortical strip for IntraOperative Neurophysiological Monitoring (IONM) to achieve CE mark under MDR (1).

Already CE marked under MDD for the EU market, FDA cleared for the US market, and TGA approved for the Australian market, the WISE Cortical Strip is intended for intraoperative use with recording, monitoring and stimulation equipment for the recording, monitoring, and stimulation of electrical signals on the brain surface during brain surgeries.

Unlike conventional cortical strips, which are made of stiff metal discs enclosed in a thick silicone foil, the WISE Cortical Strip is composed of stretchable platinum contacts embedded in a soft and thin film of silicone. As a result, the WISE Cortical Strip is highly adaptable and conformable to the brain surface ensuring unique stability and complete adhesion on the brain surface, revolutionizing intraoperative neurophysiological monitoring technology. This provides significant clinical benefits to epilepsy



WISE Cortical Strip



WISE SpA Manufacturing

surgery, by enhancing the precision of epileptogenic zone localisation and improving surgical outcomes (2) and to tumor surgery, by improving signal detection by lower impedance and better conformability to the brain (3) .

The WISE Cortical Strip is the flagship product of the company, showcasing the superior capabilities of WISE's patented Supersonic Technology to producing highly ergonomic, conformable, and minimally invasive neuroelectrodes. Supersonic Technology is already scaled to industrial production and is also at the core of the second product of the company, the Heron® lead: the first unidirectional percutaneous multicolumn lead for Spinal Cord Stimulation (SCS).

The novel certification of the product according to the Medical Device Regulation will allow WISE to speed up the development of its WISEneuro® Monitoring products family and to ensure commercialisation in Europe, and in the other markets accepting CE mark, also after the MDD transition period.

(1)According to EUDAMED register - European Medical Device Nomenclature (EMDN) N0101020101.

(2)Biagioli N et al. Epileptic Disord. 2024, 26(3):357-364, Castelli N et al. Brain and Spine 2023, 3:101794 102270., Moriconi E et al. Brain and Spine 2023, 3:101794.

(3) Kees Wim Gerritsen J et al. Acta Neurochirurgica 2019, 161:99-107, Sarnthein J et al. Clinical Neurophysiology 2022, 142:44-51, Dimakopoulos V et al. Clinical Neurophysiology 2023, 153:133-140.

About WISE: WISE SpA is a medical device company developing a new generation of implantable leads for neuromonitoring, neuromodulation and brain-machine interface (BMI). Using its patented Supersonic Technology, WISE's electrodes are highly ergonomic, conformable, soft and thin, thus allowing great adhesion, minimal invasiveness and excellent adaptability on neural tissues.

Founded in 2011 by a team of material scientists coming from the University of Milan, WISE has so far received funding from Agite!, Atlante Seed and Atlante Ventures, Indaco, Indaco Ventures I – Parallel Lombardia, b2venture, CDP Venture Capital, Eureka!, HTGF, New Frontier, Primo Venture and Wallaby. In 2016, the Company established its production plant in Cologno Monzese, Milan, Italy (2000 m² wide, comprising cleanrooms and production laboratories ISO13485 and 21 CFR compliant for the manufacturing of implantable medical devices) and has an office in Berlin, Germany.

In June 2024, WISE successfully signed a new financing round worth €25 million, comprising both

an equity investment and a venture debt loan from the European Investment Bank (EIB), supported by InvestEU.

For more information, please visit: www.wiseneuro.com.

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