DECLARATION OF CONFORMITY

We,

Fabrinal SA
Rue de la Tuilerie 42
CH-2300 La Chaux-de-Fonds
Switzerland
SRN : CH-MF-000015863
CHRN : CHRN-MF-20001578

declare under our sole responsibility that the class IIa medical device,

Product Name	ERG-Thread
Product Ref.	ET-01
Basic UDI-DI	++EFABET01TS
Intended Use	ERG-Thread is an electrode intended to be placed on the corneal or conjunctival fornix or scleral area to transmit electrical signals for subsequent measurement and recording of electroretinography (ERG), to support the diagnosis of retinal dysfunctions. It can be used to perform either full-field ERG, multifocal ERG or Pattern ERG assessment.

from 04.07.2023, meet all applicable provisions of Regulation EU 2017/745 with respect to its design and construction and to the version as commercialized. The product listed above has undergone a conformity assessment procedure per Annex IX (IX – Chapters I and III).

Notified Body	CE 0123 TüvSüd Product Service GmbH Ridlerstrasse 65 80339 Munich, Germany
Certificate	**G10 003811 0004 Rev.00**
EU – Rep	Medidee Services (Deutschland) GmbH Hohnenweg 9 78098 Triberg Baden-Württemberg, Germany SRN : DE-AR-000005578

Place, Date : La Chaux-de-Fonds, le 30.10.2023

Name, Function and Signature Cloé Houriet, Director : _____