

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-Jet
Product Ref.	F-06
Basic UDI-DI	++EFABF064B
Intended Use	The ERG-Jet is a contact lens electrode intended to be applied on the cornea and to be used for the measurement and recording of electroretinography (ERG) signals, to support the diagnosis of retinal dysfunctions. It can be used to perform either full-field or multifocal 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 : 