

DECLARATION OF CONFORMITY

We,

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

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

Product Name	ERG-Thread
Product Ref.	ET-01
Basic UDI-DI	+EFABET011
Intended Use	The ERG-Thread is used to support diagnostic systems for anomalies of the eye by transmitting the retinal electrical signal. It is indicated in various clinical situations such as the assessment of retinal functions and neurological disorders. It can be used for assessment of either ffERG, mfERG or PERG.

to which this declaration relates, is in conformity with annexes V, section 4 and VII of the EC Directive 93/42 and with current applicable harmonized standards.

Notified Body	CE 0123 TüvSüd Product Service GmbH Ridlerstrasse 65 80339 Munich, Germany
Certificate	G2 18 02 03811 002
EU – Rep	Medidee Services (Deutschland) GmbH Hohnenweg 9 78098 Triberg Baden-Württemberg, Germany SRN : DE-AR-000005578

Place, Date : La Chaux-de-Fonds, 25.11.2021

Name, Function and Signature

Cloé Houriet, Director :

