

## 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,

<b>Product Name</b>	ERG-Jet
<b>Product Ref.</b>	F06
<b>Basic UDI-DI</b>	+EFABF062
<b>Intended Use</b>	The ERG-Jet 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.

from Lot AFV 2020-05 and until July 4, 2023, is in conformity with annexes V, section 4 and VII of the EC Directive 93/42 and with current applicable harmonized standards.

<b>Notified Body</b>	CE 0123 TüvSüd Product Service GmbH Ridlerstrasse 65 80339 Munich, Germany
<b>Certificate</b>	G2 18 02 03811 002
<b>EU – Rep</b>	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 : 