EU DECLARATION OF CONFORMITY

issued on the basis of the manufacturer's exclusive responsibility

Manufacturer: **Karel Hrnčíř – BIOMAG** ID: 18848125
Chomutice 81 VAT: CZ5702232085
507 53 Chomutice Czechia

Product: **Pulsed Magnetic Therapy Device BIOMAG®**
SRN: **CZ-MF-000025009**

Model: **BIOMAG® Lumina 3D-e with applicators (trade name: Lumina 3D-e)**
A6P2, A8P, A11P, A12PM, A12PL, AL21, SL29, SL30-3D, SL30-P, SL60-P, SL70

Basic UDI: BIOMAG® Lumina 3D-e – 859420828BIOMAGLUMINA3DSA
BIOMAG® Applicators – 859420828APLIKATORVN

Classification: **Class IIa**
Classification in accordance with Annex VIII to Rule 9 of Regulation (EU) 2017/745 of 5 April 2017, as amended.

Description: The medical device is designed for additional symptomatic treatment to support the alleviation of pain, swelling, spasms and detoxification, to improve blood circulation (vasodilation) and to accelerate healing.
It is used for various health conditions involving the musculoskeletal system, for degenerative disorders and after accidents, injuries, surgical procedures, etc.

Declaration: The Declaration of Conformity is in compliance with Regulation (EU) 2017/745, of 5 April 2017, as amended.
The manufacturer confirms the assessment of the conformity of the properties with the requirements of Regulation of the European Parliament and of the Council (EU) 2017/745, as amended, which stipulates technical requirements for medical devices, and the requirements in accordance with Act 22/1997 Coll., on technical requirements for products and on the amendment and supplementation of certain acts, as amended.
Conformity was assessed in accordance with the requirements of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011, on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS), fulfilling the requirements of Delegated Directive (EU) 2015/863, which amends Annex II to Directive 2011/65/EU.

Evidence: Annex IX – Assessment of conformity based on a quality management system and on an assessment of the technical documentation of Regulation of the European Parliament and of the Council (EU) 2017/745, as amended.

Regulations:

EN 60601-1:2006/A1:2013	EN ISO 13485:2016/AC:2018
EN 60601-1-2:2015	EN ISO 14971:2019
EN 60601-1-6:2010	EN ISO 15223-1:2021
EN 60601-1-11:2010	EN ISO 10993-1:2009/AC:2010
EN 62304:2006	EN ISO 10993-5:2009

Digitally signed by Burdila Gheorghe
Date: 2024.10.04 17:25:59 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Notification: **No. 2265**
3EC International a.s.
Hraničná 18
821 05 Bratislava
Slovakia

EU Certificate: **No. 2024-MDR/QS-001**

dated 31.01.2024 valid until 31.01.2029

Date of issue: 31.01.2024

Place of issue: Jičín

biomag
507 53 Chomutice 81
IČO 188 48 125 DIČ CZ5702232085

Revision: en REV C 24/01

Signature of responsible person: **Karel Hrnčíř, director**