



EC CERTIFICATE

Full Quality Assurance System

Certificate No.:

10000367702-PA-NA-SVK rev.0.0

Project No.:

PRJN-187805-2020-PA-SVK

Valid Until:

27 May 2024

This is to certify that the quality system of:

Mandelay Kft.

Szigetszentmiklós 2310, 12001/13 Gyártelep Hrsz, Hungary

For design, production and final product inspection/testing of:

UNIVERSAL ELECTROPHYSIOLOGICAL BIOFEEDBACK SYSTEM WITH ELECTROTHERAPY FUNCTION

Has been assessed with respect to:

The conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 07 April 2021



For the issuing office:
Notified Body 2460
DNV Product Assurance AS

Sholeh Gheissar

Sholeh Gheissar
Principal Assessor

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

ICP-4-5-i1-MDD-f2, rev.0

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	07 April 2021

Products covered by this Certificate:

Product Description	Product Name	Class
Universal Electrophysiological Biofeedback System with electrotherapy function	SCIO	IIa
	Mandelay Quest 9	
	Health Optimizing Homeostasis	

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Mandelay Kft.	Huba utca 25, 2316 Tököl, Hungary

APPENDIX TO EC CERTIFICATE

Appendix to Certificate no.:
10000367702-PA-NA-SVK rev 0.0

Valid Until:
27 May 2024

This is an Appendix issued to EC Certificate issued for manufacturer:
MANDELAY Kft.

originally issued in compliance with:
the Council Directive 93/42/EEC on Medical Devices, as amended

The name or identifier of a device already covered by the certification, has been revised.

Products covered by this Certificate (replaces information on certificate):		
Product Description	Product Name	Class
Universal Electrophysiological Biofeedback System with electrotherapy function	Mandelay Q9	Ila

Appendix History -		
Revision	Description	Issued Date
0.0	Product name change	26 September 2022

Place and date:
Høvik, 26 September 2022



For the issuing office:
DNV Product Assurance AS - Notified Body
2460
Veritasveien 3, 1363 Høvik, Norway


Palani Damodharan
Principal Assessor

We confirm Validity of the appendix to EC certificate No. 10000367702-PA-NA-SVK rev.0.0

DNV Business Assurance

Czech Republic s.r.o.

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Ing. Mária Lichnerová

Country Operation Manager