



# 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](http://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 |

## Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. the Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

## Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate

Certificate No.:  
**15017-2019-AQ-CZS-NA-PS Rev. 0.0**

Project No.:  
**PRJC-601141-2019-PRC-CZE**

Initial Certification Date:  
**16 October 2019**

Valid Until:  
**16 October 2022**

This is to certify that the management system of:

## **Mandelay Kft.**

Gyártelep Hrsz. 12001/33.  
2310 Szigetszentmiklós  
Hungary

With sites as listed overleaf.

Complies with the requirements of:

## **ISO 13485:2016/NS-EN ISO 13485:2016**

The Certificate is valid for the following scope:

**Design, Development, Production, Distribution, and Service of Pulsed Electromagnetic Field devices and Universal Electrophysiological Biofeedback System with the following names: SCIO, Educator, QUEST 9, Health Optimizing Homeostasis.**

Place and Date:  
**Høvik, 16 October 2019**



For:  
**DNV GL PRESAFE AS**



**Eugenie Winger Husebye**

The Certificate has been digitally signed.  
See [www.presafe.com/digital\\_signatures](http://www.presafe.com/digital_signatures) for more info

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



# Management System Certificate

Certificate No.:  
**15017-2019-AQ-CZS-NA-PS Rev. 0.0**

Project No.:  
**PRJC-601141-2019-PRC-CZE**

Initial Certification Date:  
**16 October 2019**

Valid Until:  
**16 October 2022**

| Site Name     | Address   | Site Scope  |
|---------------|---|---|
| Mandelay Kft. | Gyártelep Hrsz.<br>12001/33.,2310,Szigetszentmiklós,Hungary | Registration address  |
| Mandelay Kft. | Huba utca 25.,2316,Tököl,Hungary                            | Design, Development, Production, Distribution, and Service of Pulsed Electromagnetic Field devices and Universal Electrophysiological Biofeedback System with the following names: SCIO, Eductor, QUEST 9, Health Optimizing Homeostasis. |

End of Certificate

# MANAGEMENT SYSTEM CERTIFICATE

Certificate No:  
285665-2019-AQ-BUD-RvA

Initial certification date:  
17 June 2019

Valid:  
17 June 2019 - 16 July 2022

This is to certify that the management system of

## Mandelay Kft.

2316 Tököl, Huba utca 25., Hungary  
and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:  
**ISO 9001:2015**

This certificate is valid for the following scope:

**Design, development, production, distribution, and service of Universal  
Electrophysiological Biofeedback Systems with electrotherapy function**

Place and date:  
**Budapest, 17 June 2019**



The RvA is a signatory to the IAF MLA

For the issuing office:  
**DNV GL – Business Assurance**  
**1143 Budapest XIV, Stefánia út 101-103.,**  
**Hungary**

**Adlovits László**  
Management Representative

Certificate No: 285665-2019-AQ-BUD-RvA  
Place and date: Budapest, 17 June 2019

## Appendix to Certificate

### Mandelay Kft.

Locations included in the certification are as follows:

| Site Name     | Site Address   | Site Scope  |
|---------------|--|---|
| Mandelay Kft. | 2316 Tököl, Huba utca 25., Hungary                         | Design and development, production, distribution and service of Universal Electrophysiological Biofeedback Systems with electrotherapy function |
| Mandelay Kft. | 2310 Szigetszentmiklós, Gyártelep Hrsz. 12001/33., Hungary | Registration Address  |

