3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia
Notified Body No. 2265

EC CERTIFICATE

No. 2019-MDD/QS-036

issued in compliance with the Council Directive 93/42/EEC as amended by 2007/47/EC, which is implemented by the Slovak Government Decree No. 582/2008 Coll. as amended by 215/2013 Coll. certifies that the medical device of Class IIa,

Electroencephalograph EEG: *Type Unique+, Sienna, Sienna ULTIMATE*
Electromyograph and Evoked Potential Equipment EMG/EP: *Type Surpass, Surpass LT*
Electrical Impedance Segmentograph EIS: *Type Angelie EIS*
Neurostimulator: *Type EMS Neurostimulator*

manufactured by the company

EMS Handels Gesellschaft m.b.H.
Jochingergasse 1, A-2100 Korneuburg, Austria

is manufactured under conditions fulfilling the quality system requirements of Annex II, excluding (4), of the Directive 93/42/EEC as amended by 2007/47/EC.

The Notified Body No. 2265 has performed an audit of the above device quality system. The full quality assurance system has been assessed and found that it meets the requirements above. The quality system is subject to continuous surveillance according to Annex II, Sections 3.3, and 5, of the Directive 93/42/EEC as amended by 2007/47/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. 310376 and the Final protocol No. 310376/2019.

This certificate is issued under the following conditions:

It applies only to the quality system maintained in the manufacture of the above referenced model of medical device and it does not substitute the design or type-examination procedures, if requested. The certificate remains valid until the manufacturing conditions or the quality system are changed but until April 28, 2024 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfilment of relevant legal and other requirements by manufacturer.

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

Dr. Katarina Tomin Srdošová
Responsible to act on behalf of NB 2265

In Bratislava, on April 29, 2019

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3EC International a.s., Hraničná 18, 821 05 Bratislava, Slowakei
Benannte Stelle (NB) Nr. 2265

EG ZERTIFIKAT

Nr. 2019-MDD/QS-036

in Übereinstimmung mit der Richtlinie 93/42/EWG in der Fassung 2007/47/EG, die als slowakische Regierungsverordnung Nr 582/2008 umgesetzt und durch Fassung 215/2013 ergänzt wurde, bestätigt hiermit, dass die Medizinprodukte der Klasse IIa,

Elektroenzephalograph EEG: *Typ Unique+, Sienna, Sienna ULTIMATE*
Elektromyograph und Evozierte Potentiale Gerät EMG / EP:
Typ Surpass, Surpass LT
Elektrische Impedanz Segmentograph EIS: *Typ Angelie EIS*
Neurostimulator: *Typ EMS Neurostimulator*

hergestellt von

EMS Handels Gesellschaft m.b.H.
Jochingergasse 1, A-2100 Korneuburg, Austria

unter den Bedingungen des Qualitätssicherungssystem nach den Anforderungen des Anhangs II, mit Ausnahme des Punktes (4), der Richtlinie 93/42/EWG ergänzt nach 2007/47/EG Fassung hergestellt werden.

Die benannte Stelle No. 2265 hat das Audit des Qualitätssicherungssystems unter dem die oben genannten medizinischen Produkte hergestellt werden, durchgeführt. Die vollständige Qualitätssicherung wurde beurteilt und es wurde festgestellt, dass die oben angegebenen Anforderungen erfüllt sind. Das Qualitätsmanagementsystem unterliegt kontinuierlicher Überwachung nach Anhang II, Abschnitte 3.3 und 5 der Richtlinie 93/42/EWG ergänzt durch 2007/47/EG. Die detaillierte Beschreibung des Systems, der erfüllten Anforderungen und der umgesetzten Maßnahmen des Herstellers sind in dem Auditbericht Nr. 310376 und dem Schlussprotokoll Nr. 310376/2019 angegeben.

Dieses Zertifikat wird unter den folgenden Bedingungen erteilt:

Es gilt nur für das Qualitätssicherungssystem für die Herstellung der oben genannten Modelle der medizinischen Produkte und es ersetzt nicht die Auslegung der Produkte und EG-Baumusterprüfung Verfahren, wenn diese anwendbar sind. Das Zertifikat bleibt gültig, bis die Herstellungsbedingungen oder das QM-System geändert werden, aber spätestens bis 28. April 2024. Die Gültigkeit des Zertifikats ist bedingt durch positive Ergebnisse der regelmäßigen Überwachungsaudits und der Erfüllung der relevanten gesetzlichen und anderer Anforderungen durch den Hersteller.

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

Dr. Katarína Tomin Srdošová
Zuständig im Auftrag der Benannten Stelle (NB) 2265 zu handeln

In Bratislava, am 29. April 2019

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Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	EMS Handels Gesellschaft m.b.H.
Manufacturer address and contact details	Jochingergasse 1, 2100 Korneuburg, Austria +43 2262 61655-0 Email: office@emsbiomed.com
Single Registration Number (SRN) (if available)	AT-MF-000002599

Authorised Representative name (if applicable)	n.a.
Authorised Representative address and contact details	n.a.
Single Registration Number (SRN) (if available)	n.a.

Notified body name (if applicable)	□ See attached schedule
Notified body number (if applicable)	

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

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	□ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	□ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	□ See attached schedule
End date of extended validity/transition period	□ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

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☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

☒Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☒Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

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Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☒ A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

EMS Handels Gesellschaft m.b.H.

Korneuburg, 17.04.2024

Ppa. Ruzena Ortnerova

Authorized officer

X

ppa. Ruzena Ortnerova
authorized officer

Contact Details: ruzena.ortner@emsbiomed.com
Phone: +43 2262 61655-0

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Electromyograph and Evoked Potential Equipment EMG/EP Trade name: Surpass, Surpass LT	2019-MDD/QS-036	28.04.2024	3EC International a.s. NB2265	3EC International a.s. NB2265	31st of December 2028	n.a.
Electroencephalograph EEG Trade name: Sienna, Sienna ULTIMATE	2019-MDD/QS-036	28.04.2024	3EC International a.s. NB2265	3EC International a.s. NB2265	31st of December 2028	n.a.
Electroencephalograph EEG Trade name: Unique+	2019-MDD/QS-036	28.04.2024	3EC International a.s. NB2265	3EC International a.s. NB2265	31st of December 2028	n.a.
Neurostimulator Trade name: EMS Neurostimulator	2019-MDD/QS-036	28.04.2024	3EC International a.s. NB2265	3EC International a.s. NB2265	31st of December 2028	n.a.
Electrical Impedance Segmentograph EIS Trade Name: Angelie EIS	2019-MDD/QS-036	28.04.2024	3EC International a.s. NB2265	3EC International a.s. NB2265	31st of December 2028	n.a.

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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international

EMS Handels Gesellschaft m.b.H
Jochingergasse 1,
2100 Korneuburg,
Austria

Attn. Alfred Ortner/ Chief Executive Officer

Our reference	***Contact person***	BRATISLAVA
MIT/2024/P053	Michal Tomin / +421 915 366 774	20.2.2024

Subject: Notified Body Confirmation Letter

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as amended as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **3EC International a.s.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2265 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

EMS Handels Gesellschaft m.b.H

Jochingergasse 1,

2100 Korneuburg,
Austria

SRN Number (if available): AT-MF-000002599

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices

- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Katarína Tomin Srdošová, PhD.
Director of NB2265

3EC International a.s. ④
Hraničná 18, 821 05 Bratislava
Slovak Republic
ID No.: 36 789 003
VAT No.: SK2022390073

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Electromyograph and Evoked Potential Equipment EMG/EP Trade name: Surpass, Surpass LT	Class IIa	N/A	2019-MDD/QS-036, NB2265
Electroencephalograph EEG Trade name: Sienna, Sienna ULTIMATE	Class IIa	N/A	2019-MDD/QS-036, NB2265
Electroencephalograph EEG Trade name: Unique+	Class IIa	N/A	2019-MDD/QS-036, NB2265
Neurostimulator Trade name: EMS Neurostimulator	Class IIa	N/A	2019-MDD/QS-036, NB2265
Electrical Impedance Segmentograph EIS Trade name: Angelie EIS	Class IIa	N/A	2019-MDD/QS-036, NB2265

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/2/20	MIT/2024/P053	Initial issue