Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. TR-1 din 13.07.2023

Solicitantul TRIUMF MOTIV SRL, cu sediul or. Chișinău str. Grenoble 193
(adresa)
_____, tel./fax: 022768462, e-mail triumf.motiv@mail.ru,
solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Eroscan	Portable Otoacoustics Test Device

Se anexează următoarele acte:
DECLAȚIE DE CONFORMITATE CE
CERTIFICATUL DE CONFORMITATE CE
Scrisoare de autorizare de la producător

Data 13.07.2023 Semnătura _____

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Digitally signed by Jighili Tatiana
Date: 2023.07.14 09:50:13 EEST
Reason: MoldSign Signature
Location: Moldova

Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: _____TRIUMF MOTIV SRL_____, cu sediul _____or. Chișinău str. Grenoble 193_____,

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

Eroscan	Portable Otoacoustics Test Device

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia Jighili Tatiana, Administrator
Semnătura _____

Data _13.07.2023___

LETTER OF AUTHORIZATION

We hereby declare that

Triumf-Motiv SRL
Grenoble street 193 of. 1301
MD-2043 Kishinev
Moldova

is authorized to promote, offer, and sell MAICO Audiometers, Impedance Meters, Otoacoustic Emissions Systems OAE and Auditory Brainstem Measuring Systems ABR in Moldova.

Products supplied:	MAICO Audiometers, Impedance Meters, OAE and ABR measuring systems
Origin of products:	European Union
Seller of MAICO products:	MAICO Diagnostics GmbH / Federal Republic of Germany

Triumf-Motiv SRL is obligated to provide information about the final destination of the goods and to ensure that the end customer receives an instruction according to the operation manual of the device.

This agreement will be effective until 31st of December 2023. It will be automatically renewed for periods of one year each unless terminated with or without cause by either Triumf-Motiv SRL or MAICO Diagnostics GmbH upon 120 days written notice to the other party.

Berlin shall be the exclusive place of jurisdiction for all disputes arising from this agreement.

MAICO Diagnostics GmbH

Angela Röske
Head of Customer Support

MAICO Diagnostics GmbH
Sickingenstraße 70-71
10553 Berlin
Germany
Tel.:+49 30- 70 71 46-50 Fax: +49 30- 70 71 46-99

Berlin, 11th July 2023

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 063429 0017 Rev. 01

Holder of Certificate: **MAICO Diagnostics GmbH**

Sickingenstr. 70-71
10553 Berlin
GERMANY

Certification Mark:

Scope of Certificate: **Design and development, manufacture, sales and servicing of audiometric equipment for the area of audiology**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 063429 0017 Rev. 01

Report No.: 713242207, 713274290

Valid from: 2023-03-02
Valid until: 2026-03-01

Date, 2023-03-02

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 063429 0017 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

MAICO Diagnostics GmbH
Sickingenstr. 70-71, 10553 Berlin, GERMANY

Design and development, marketing and sales of audiometric equipment

DGS Diagnostics Sp. z o. o.
Rosówek 43, 72-001 Kolbaskowo, POLAND

Manufacture, distribution and servicing of audiometric equipment

DGS Diagnostics A/S
Audiometer Allé 1, 5500 Middelfart, DENMARK

Design and development, manufacture of audiometric equipment

Parameters:

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

EU Declaration of Conformity

It has been demonstrated that:

Product:

Product name:	EROSCAN
Product type:	Portable Otoacoustics Test Device
Intended purpose:	Hearing assessment
Trademark:	MAICO
Class.:	IIa
Basic UDI-DI:	426017612_8104863_25

Manufactured by:

Name:	**MAICO Diagnostics GmbH**	SRN:	**DE-MF-000006145**
Address:	**Sickingenstr. 70-71**	Phone No.:	**(+49) 30 7071460**
Area code/Area:	**10553 Berlin**	Fax No.:	**(+49) 30 70714699**
State/Country:	**Germany**		

Is in conformity with the European Regulation (EU) 2017/745 and Directive 2011/65/EU.

Conformity assessment:	Annex IX (Quality system and technical documentation assessment)
EU-Certificate No.:	G10 063429 0018 Rev. 00
Valid until:	2026-06-09

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstrasse 65, 80339 Munich / Germany
ID no. 0123

This declaration is issued on the sole responsibility of:

Company:	**MAICO Diagnostics GmbH**
Address:	**Sickingenstr. 70-71**
Address:	**10553 Berlin**
State/Country:	**Germany**

Signature: 

Place: Berlin

Date: 2021-07-28 (YYYY-MM-DD)

Name: **Uwe Ledworuski**
Title: **Head of Quality & Regulatory**

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Product Service

Confirmation Statement related to the EU Certificate (MDR)

List of Sites involved in the Product Realisation Processes

No. GRS 063429 0019 Rev. 02

Manufacturer:

MAICO Diagnostics GmbH
Sickingenstr. 70-71
10553 Berlin
GERMANY

This List of Sites is only valid in combination with the following EU Certificate (MDR):

G10 063429 0018 Rev. 00

The following pages list all sites under the manufacturer's quality system where product realisation processes are conducted for those devices covered by the aforementioned EU Certificate pursuant to the Regulation (EU) 2017/745 (MDR) on medical devices.

Report No.: 713297269

Valid until: 2026-06-09

M. Häuserer

Issue Date: 2023-04-03

(Mirjam Häuserer)
PS-MHS-FA-0 – Foreign Affairs

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Product Service

Confirmation Statement related to the EU Certificate (MDR)

List of Sites involved in the Product Realisation Processes

No. GRS 063429 0019 Rev. 02

Sites:

MAICO Diagnostics GmbH
Sickingenstr. 70-71, 10553 Berlin, GERMANY

DGS Diagnostics A/S
Audiometer Allé 1, 5500 Middelfart, DENMARK

DGS Diagnostics Sp. z o. o.
Rosówek 43, 72-001 Kolbaskowo, POLAND

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