EC CERTIFICATE

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

No. 5-792-200-1608

National Institute of Pharmacy and Nutrition
Directorate of Device Testing and Clinical Engineering (EMKI)

certifies that the manufacturer:

MEDIROLL Orvostechnikai Kft.
Postakert u. 10.
4025 Debrecen
Hungary

for the products / product category:

Medical diagnostic and therapeutic devices

applies a quality system which meets the requirements of Directive 93/42/EEC concerning medical devices, Annex II.

Registry number of the related audit report: **42-8181-2016**

This certificate is valid until **2021-08-16** supposed that the results of the regular yearly surveillance audits are satisfactory.

Issued by EMKI as a Notified Body with identification number **1011**.

This certificate is valid only with the attachment.

Budapest, 2016-08-17

Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet Eszközminősítő és Kórháztechnikai Igazgatóság

Deputy General Director | Head of EMKI | EMKI 1517

The authenticity and validity of the certificate are verifiable at EMKI.

Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet
National Institute of Pharmacy and Nutrition
Eszközminősítő és Kórháztechnikai Igazgatóság
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H-1051 Budapest, Zrínyi u. 3. Fax: +36 1 886 94 60, Telefon: +36 1 225 27 39
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OGYÉI
EMKI

ATTACHMENT TO EC CERTIFICATE

Additional information for Certificate No. 5-792-200-1608

The certificate is valid for the following products / models:

Medical diagnostic and therapeutic devices

	Type	*Class*
Portable screening audiometer	SA-7	IIa
Portable screening / diagnostic audiometer	SA-52	IIa
Clinical audiometer	AT-61	IIa
Fluid warmer device	VM-1	IIa

The detailed description of the products is kept by EMKI under No. 42-8181-2016.

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Deputy General Director Head of EMKI EMKI

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