Medical Products Research Srl

Tel. +39.0331.597992 http://www.mpr-italy.it
e-mail: info@mpr-italy.it Fax +39.0331.485089

To whom it may concern,

Legnano, 18/03/2024

EU Regulation 2023/607: Extension of validity EC certificates issued in accordance with Directive 93/42/EEC

Medical Products Research srl, with registered office in Legnano (MI), Piazza San Magno 7, as manufacturer of medical devices, covered by EC certificate DD60144931 issued in accordance with Directive 93/42/EEC,

DECLARES

- To be in possession of the EC conformity certificates issued in accordance with Directive 93/42/EEC by the Notified Body TUV Rheinland Italia Srl with identification number 1936, still valid and not revoked to date;

- To have submitted a formal application to the Notified Body ICIM Spa with identification number 0425 in accordance with section 4.3, first paragraph of Annex VII MDR, for conformity assessment by 26 May 2024 for devices in Annex A;

- To have signed an agreement in accordance with section 4.3, second paragraph of Annex VII MDR, before 26 September 2024 with the notified body ICIM Spa with identification number 0425 for devices in Annex A;

- That there are no significant changes in the design and intended purpose of the devices;

- That the devices do not present an unacceptable risk to the health or safety of patients, users or other persons or to other aspects of public health protection;

- That a quality management system (QMS) is in place in accordance with Article 10(9).

As the requirements of EU Regulation 2023/607 are met, the validity of certificate DD60144931 is extended until 31 December 2028, the date by which all the devices covered by the certificate may be placed on the market.

In witness whereof,

Firmato digitalmente da Diego Martinengo

Diego Martinengo
Legal representative

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e-mail: info@mpr-italy.it Fax +39.0331.485089

ANNEX A

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)
FREE ASPIRE ADVANCED **EFA**	Class IIa
FREE ASPIRE HYBRID **KALOS** **IE PLUS** **KINEX** **KALOS ADVANCED**	Class IIa
MPR700 - TPEP®ADVANCED I/E **TPEP®4** **TPEP® ONE**	Class IIa
VAKUM **DYSPH-AIDE** **FLOW KLEANER** **KLEANER**	Class IIa
FREE FLOW **LIFE FLOW EFA®** **FLOWTHERM 60 EFA®** **LIFE FLOW** **FLOWTHERM 60** **H-FLOW**	Class IIa
SUCTION FREE mod MPR224, MPR225, MPR226, MPR227, MPR228, MPR229	Class IIa
KFA/F, KFAA	Class IIa
MPR201, MPR202, UNIKIT, MPR208, MPR282 **MPR712, MPR713, MPR714, MPR715** **KFAH, KFAH/FA, KFAH/PF, MPR345UK**	Class IIa
KVAK, KVAK/FA, KVAK/V, KVAK/S, KVAK/SV	Class IIa
KHFL/M, KHFL/A, KHFL, KHFL/HFM, KHFL/HFA, KHFL/PM, KHFL/PA, KHFL/HT, KHFL/HTP, KHFL/30, KHFL/CM, KHFL/CA, KHFL/EFA	Class IIa
FREE ASPIRE **SUCTION FREE COMPRESSOR**	Class IIa
UNIKO-TPEP® E **TPEP®Avant** **TPEP®ADVANCED I/E**	Class IIa

Certificato di conformità CE

EC Certificate of Conformity

TÜVRheinland®

Garanzia di qualità della produzione secondo la direttiva 93/42/CEE allegato V

EC Directive 93/42/EEC Annex V Production Quality Assurance Medical Devices

Certificato n°: **DD 60144931**
Registration No:

Fabbricante: **Medical Products Research S.r.l.**
Manufacturer:

Sede legale: **Piazza San Magno 7**
Registered Headquarter: **20025 Legnano (MI) - Italia**

Sede operativa: **Via Novara, 68**
Operational Headquarter: **20025 Legnano (MI) - Italia**

Scopo: **Dispositivi attivi per apparato respiratorio /** *Respiratory devices*
Scope:

Dispositivi non attivi per infusione/ *Non-active devices for infusion*

(Vedere allegato tecnico al presente Certificato per tipologie, modelli e codici)
(*See the attachment for typologies, models and codes designation)*

L'organismo notificato dichiara che il Sistema di qualità stabilito ed applicato dalla società sopra specificata soddisfa i requisiti dell'allegato V della suddetta direttiva. Questa approvazione è soggetta a sorveglianza periodica, così come definita nell'allegato V, articolo 4 della suddetta direttiva e può essere utilizzata congiuntamente alla dichiarazione di conformità redatta dal fabbricante. */ The Notified Body hereby declares that the requirements of annex V of the Directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned Directive and can be used in conjunction with the conformity declaration issued by the Manufacturer.*

L'organismo notificato/ *Notified Body*

Data di emissione/*Issue date*: **08/01/2020**
Data di ultima modifica/*Last revision date:* **17/06/2020**
Data di scadenza/*Expiry date:* **26/05/2024**

Paolo Caglio

TÜV Rheinland Italia S.r.l. Certification Body

TÜV Rheinland Italia S.r.l. - Via Mattei, 3 - 20010 - Pogliano Milanese (MI)
Autorizzata dal Ministero della Salute e dal Ministero dello Sviluppo Economico
Accredited by Ministry of Health and by Ministry of Economic Development

Organismo notificato con il numero 1936 presso la Commissione Europea
Notified under No. 1936 to the EC Commission

CE La marcatura CE può essere apposta esclusivamente se vengono soddisfatti i requisiti di tutte le direttive CE applicabili CE
The CE marking may be used if all relevant and effective EC Directives are complied with

Fabbricante/*Manufacturer:* **Medical Products Research S.r.l.**

Scopo/*Scope:* **Dispositivi attivi per apparato respiratorio /** *Respiratory devices*

Tipologia/ *Typology:* **Aspiratore delle secrezioni delle vie respiratorie /** *Device for removal of respiratory secretions*

Modello/ *Model:*

Free Aspire, Suction free compressor, Free Aspire Advanced, EFA

Tipologia/ *Typology:* **Apparecchi a pressione positiva intermittente (IPPB) con TPEP® per terapia respiratoria e per aerosolterapia /** *Intermittent positive pressure (IPPB) equipment with TPEP® for respiratory therapy and aerosol therapy*

Modello/ *Model*

Uniko-Tpep®E, TPEP® Avant, TPEP® ADVANCED I/E, MPR700-TPEP®ADVANCED I/E, TPEP® 4, TPEP® ONE

Tipologia/ *Typology:* **Dispositivo per la rimozione delle secrezioni tracheo-bronchiali /** *Device for removal of trachea-bronchial secretions*

Modello/ *Model:*

Suction Free mod: MPR224, MPR225, MPR226, MPR227, MPR228, MPR229

Tipologia/ *Typology:* **Dispositivo per la disostruzione bronchiale /** *Device for the bronchial unblocking*

Modello/ *Model:*

Free Aspire Hybrid, Kalos, IE Plus, Kinex, Kalos Advanced

L'organismo notificato
Notified Body

Data di ultima modifica: **17/06/2020**
Last revision date:

Tipologia/ *Typology:* **Dispositivi non attivi per ginnastica respiratoria e rimozione delle secrezioni/** *Non-active devices for respiratory gymnastics and removal of secretions*

Codici/ *Codesl:*

KFA, KFA/F, KFAA

MPR201, MPR202, UNIKIT, MPR208, MPR282,

MPR712, MPR713, MPR714, MPR715

KFAH, KFAH/FA, KFAH/PF, MPR345UK(*)

Tipologia/ *Typology:* **Dispositivo per la disostruzione delle vie aeree e aspirazione delle secrezioni /** *Device for the destruction of the airways and aspiration of secretions*

Modello/ *Model:*

VAKUM, DYSPH-AIDE, FLOW KLEANER, KLEANER

Tipologia/ *Typology:* **Dispositivi non attivi per la disostruzione delle vie aeree e aspirazione delle secrezioni /** *Non active Device for the destruction of the airways and aspiration of secretions*

Codici/ *Codesl:*

KVAK, KVAK/FA, KVAK/V, KVAK/S, KVAK/SV

(*) Codice valido per tutte le tipologie certificate ad eccezione degli apparecchi a pressione positiva con tecnologia TPEP®

L'organismo notificato
Notified Body

Data di ultima modifica: **17/06/2020**
Last revision date:

TÜV Rheinland Italia S.r.l.

Allegato tecnico al Certificato n° DD 60144931

Attachment to the certificate:

TÜVRheinland®

Tipologia/ *Typology:* **Umidificatore con generatore incorporato per la somministrazione di alti flussi respiratori** / *Humidifier with built-in generator for the administration of high respiratory flows*

Modello/ *Model:*

Free Flow, LifeFlow EFA®, FLOWTHERM 60 EFA®, LifeFlow, FLOWTHERM 60, H-FLOW

Tipologia/ *Typology:* **Kit per umidificatore** / *Kit for humidifier*

Codici/ *Codes:*

KHFL/M, KHFL/A, KHFL, KHFL/HFM, KHFL/HFA, KHFL/PM, KHFL/PA, KHFL/HT, KHFL/HTP, KHFL/30, KHFL/CM, KHFL/CA, KHFL/EFA

L'organismo notificato
Notified Body

TÜV Rheinland Italia S.r.l. Certification Body

Data di ultima modifica: **17/06/2020**
Last revision date:

MEDICAL PRODUCTS RESEARCH SRL
Via Novara 68
20025 Legnano MI

18/03/2024

Notified Body Confirmation Letter
Reference: 145426 / 24

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 regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, ICIM SPA, Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0425 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:

MEDICAL PRODUCTS RESEARCH SRL
Via Novara 68
20025 Legnano MI

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for 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 ICIM 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 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 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,

ICIM SPA
Piazza Don Enrico Mapelli, 75
2099 Sesto San Giovanni MI
Identification on NANDO CE0425

Table 2: Devices covered by this letter and for which ICIM SPA 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
FREE ASPIRE ADVANCED EFA	Class IIa	N/A	Certificate N. DD60144931 Notified Body : TÜV Rheinland Italia CE1936
FREE ASPIRE HYBRID KALOS IE PLUS KINEX KALOS ADVANCED	Class IIa	N/A	Certificate N. DD60144931 Notified Body : TÜV Rheinland Italia CE1936
MPR700 - TPEP®ADVANCED I/E TPEP®4 TPEP® ONE	Class IIa	N/A	Certificate N. DD60144931 Notified Body : TÜV Rheinland Italia CE1936
VAKUM DYSPH-AIDE FLOW KLEANER KLEANER	Class IIa	N/A	Certificate N. DD60144931 Notified Body : TÜV Rheinland Italia CE1936
FREE FLOW LIFE FLOW EFA® FLOWTHERM 60 EFA® LIFE FLOW FLOWTHERM 60 H-FLOW	Class IIa	N/A	Certificate N. DD60144931 Notified Body : TÜV Rheinland Italia CE1936
SUCTION FREE mod MPR224, MPR225, MPR226, MPR227, MPR228, MPR229	Class IIa	N/A	Certificate N. DD60144931 Notified Body : TÜV Rheinland Italia CE1936
KFA/F, KFAA	Class IIa	N/A	Certificate N. DD60144931

ICIM SpA Società soggetta all'attività di direzione e coordinamento di ICIM GROUP Srl
Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI) - Tel. +39 02 725341 Fax +39 02 72002098 - www.icim.it - info@icim.it
Capitale sociale € 260.000,00 int. versato ed esistente - C.F./P.IVA e Iscriz. Reg. Imprese di Milano n. 12908230159 – R.E.A. n. 1596292

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
MPR201, MPR202, UNIKIT, MPR208, MPR282 MPR712, MPR713, MPR714, MPR715 KFAH, KFAH/FA, KFAH/PF, MPR345UK			Notified Body : TÜV Rheinland Italia CE1936
KVAK, KVAK/FA, KVAK/V, KVAK/S, KVAK/SV	Class IIa	N/A	Certificate N. DD60144931 Notified Body : TÜV Rheinland Italia CE1936
KHFL/M, KHFL/A, KHFL, KHFL/HFM, KHFL/HFA, KHFL/PM, KHFL/PA, KHFL/HT, KHFL/HTP, KHFL/30, KHFL/CM, KHFL/CA, KHFL/EFA	Class IIa	N/A	Certificate N. DD60144931 Notified Body : TÜV Rheinland Italia CE1936
FREE ASPIRE SUCTION FREE COMPRESSOR	Class IIa	N/A	Certificate N. DD60144931 Notified Body : TÜV Rheinland Italia CE1936
UNIKO-TPEP® E TPEP®Avant TPEP®ADVANCED I/E	Class IIa	N/A	Certificate N. DD60144931 Notified Body : TÜV Rheinland Italia CE1936

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/05/31	124738	Initial issue
18/03/2024	145426	Addition of device: - FREE ASPIRE / SUCTION FREE COMPRESSOR Z - UNIKO-TPEP® E / TPEP®Avant / TPEP®ADVANCED I/E

Remaining at your disposal for any clarification on the content of this letter, we take this opportunity to extend our best regards.

Mr. Edoardo Dossena
Sales Responsable Manager
Straytegic Industry
ICIM S.p.A.

Miss. Flavia Lepore
Sales Director
ICIM S.p.A.

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