May 23rd , 2024

C/0394/24/GF/vc

To: **MEDIQUA S.R.L.**
VIA RAGUSA, 13/A
00041- ALBANO LAZIALE (RM)

Bureau Veritas Italia SpA

**Notified Body Confirmation Letter** with reference to the CE Marking **Certificate n°. IT306264-1 - Directive 93/42/EEC (MDD)**

This letter confirms that, Bureau Veritas Italia SpA, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1370 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 n. n. 5390865 rev.2 in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

MEDIQUA S.R.L.
VIA RAGUSA, 13/A
00041- ALBANO LAZIALE (RM)
ITALY

Tabella n.1

| **Device name or Basic UDI-DI (under MDR application)** | **MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)** | **Device name under MDD corresponding to the device under MDR application** | **MDD/AIMDD Certificate Reference(s) of the devices under MDR application** |
|---|---|---|---|
| STERILIZZATRICE A VAPORE SERIE “STEAM” | IIb | Steam sterilizers ‘STE1’, ‘STE2’. | Certificate n° IT306264-1 issued on 2021/05/10 |

Digitally signed by Latîşev Anastasia
Date: 2025.04.16 18:17:12 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

In accordance with EU Regulation 2023/607 of the European Parliament of the Council of 15 March 2023, Bureau Veritas Italia hereby confirms that:

a. The above-mentioned agreement n. 5390865 rev.2 was signed within 2024/09/26.
b. Bureau Veritas Italia Spa is responsible for the appropriate surveillance of medical devices certified under Directive 93/42/EEC and subsequent amendments, corresponding to medical devices for which an agreement has been signed for certification according to EU Regulation 2017/745 (MDR) as shown in table n.1

As required by EU Regulation 2023/607, the validity of the MDD certificate n° IT306264-1 is extended until 2028/12/31, assuming that the manufacturer continues to comply with all the applicable conditions specified by EU Regulation 2023/607.

**Confirmation Letter Revision History**

| Date | Revision | Action |
|---|---|---|
| 2024/05/23 | 0 | Initial issue |

GLORIA FOCETOLA - Local Technical Manager

**Bureau Veritas Italia S.p.A.**
Viale Monza, 347
20126 Milano
www.bureauveritas.it

Tel. (+39) 02 27091.1
Fax (+39) 02 2552980
info.bv.italia@it.bureauveritas.com

Cap. Soc. € 4.472.131,00 i.v.
Reg. Imp. e P.IVA 11498640157
Altre Sedi: www.bureauveritas.it/sedi

Soggetta all'attività di direzione e coordinamento da parte di Bureau Veritas SA con sede in Neuilly-sur-Seine - Francia

**BUREAU VERITAS**
**Certification**

# MEDIQUA S.R.L.

VIA RAGUSA, 13/A – 00041 ALBANO LAZIALE (RM) - ITALY

**Certified site:**

VIA RAGUSA, 13/A – 00041 ALBANO LAZIALE (RM) - ITALY

*Bureau Veritas Italia S.p.A. certifies that the Full Quality Assurance System of the above organization has been audited and found to be in accordance with the requirements of*

# DIRECTIVE 93/42/EEC

*(in accordance with Annex II - excluding paragraph 4)*

*In relation to the following products*

| | |
|---|---|
| Product subcategory : | Active devices for disinfection and sterilisation |
| Generic group: | Steam sterilizers |
| Model: | STE1, STE2 |
| Class: | IIb |

Reference BV practice: ZIG. N. **9578393**

Original cycle start date: **10 May 2021**

Expiry date of previous cycle: **N/A**

Certification / Recertification Audit date: **2 April 2021**

Certification / Recertification cycle start date: **10 May 2021**

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **26 May 2024**

**Certificate No. - Version: IT306264-1** Revision date: **10 May 2021**

***GIORGIO LANZAFAME– Local Technical Manager***

*This certificate is issued by Bureau Veritas Italia S.p.A. Viale Monza, 347-20126 Milan, as a notified body for the Directive 93/42/EEC, with identification number 1370*

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation.
To check this certificate validity please refer to the website www.bureauveritas.it