

To whom it may concern

Validity declaration of CE certificate EPT 0477.MDD.21/4446

Manufacturer/Origin/MAH: AL.CHI.MI.A. S.r.l./Italy

Products: Ophthalmic Surgery, Eye and Tissue banking Devices

We, AL.CHI.MI.A. S.r.l., hereby declare that the current CE certificate: **EPT 0477.MDD.21/4446**, according to Medical Device Directive 93/42/EEC, is valid until May 26th, 2024.

However, according to Regulation (EU) 2023/607, Art.1, Par.2:

“Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC from 25 May 2017 that were still valid on 26 May 2021 and that have not been withdrawn shall remain valid after the end of the period indicated on the certificate until the date set out in paragraph 3a¹ of this Article applicable for the relevant risk class of the devices.”

the validity of CE certificate: **EPT 0477.MDD.21/4446** is extended till **31 December 2027** for class IIb implantable devices² and till **31 December 2028** for class IIa³ devices and for class I devices placed on the market in sterile condition⁴.

Please be confirmed that conditions set out under *paragraph 3c* of the same article are duly fulfilled.

At now an official letter from Eurofins Product Testing Italy, Notified Body N. 0477 regarding CE certificate extension is not yet available.

However, you can find in **Figure 1** the first page of the contract signed with Eurofins regarding MDR certification according to Regulation (EU) 2017/745.

Please note that medical devices that will be promoted from class IIa according to MDD⁵, to class III according to MDR, will be certified by a different Notified Body.

¹ Art.1, Par. 3.a: Devices which have a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and that is valid by virtue of paragraph 2 of this Article, may placed on the market or put into service until the following dates: a) **31 December 2027**, for all **class III** devices, and for **class IIb** implantable devices except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors; (b) **31 December 2028**, for **class IIb** devices other than those covered by point (a) of this paragraph, for **class IIa** devices, and for **class I** devices placed on the market in **sterile** condition or having a measuring function.

² Gases and Silicone Oils

³ Perfluorocarbons, Retinal dyes, Gas injection set (GIS), eyeDRO, Kerasave, Corneal Chamber, PSS-L, CRYO.ON, GLYO.ON, BASE, BASE 128

⁴ Easy connection tubing (ECT), Perfluorocarbon filter (PCF), Ocigel, Corneal Float

⁵ Kerasave, Corneal Chamber, PSS-L, CRYO.ON, GLYO.ON, BASE, BASE 128

We hope you can find this information satisfactory and should you need further details, please do not hesitate to contact us.

Yours Sincerely,

Ponte San Nicolò, 17 APR. 2024

Stamped: **AL.CHI.MI.A. S.r.l.**
Viale Austria, 14
35020 Ponte San Nicolò (PD)
Tel. 049.8962074 - Fax 049.8962071
Partita IVA 00063370282



Patrick Quero
QA-RA Director

List of Enclosures:

- **Fig.1**_First page of the signed contract with Eurofins Notified Body N 0477 for MDR certification.

Figure 1 – First page of the signed contract with Eurofins Notified Body N 0477 for MDR certification



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15 Novembre 2023

Prog. 22Q07815 Rev.02

Oggetto: Attività di Organismo Notificato Europeo (N° 0477) per la Certificazione CE secondo Allegato IX del Regolamento (UE) 2017/745 con riferimento ai seguenti Dispositivi Medici (DM):

- Cfr elenco Cap. 1

NOTA: la presente quotazione, in caso di accettazione, andrà ad integrare o sostituire il precedente contratto con Voi in essere Prog. 22Q07815 Rev.01.

Come da accordi intercorsi, Vi confermiamo la disponibilità a fornirVi le attività in oggetto, secondo la seguente proposta operativa ed economica.

In caso di accettazione Vi preghiamo di renderci la presente timbrata e firmata via fax allo 011.22.22.226 ovvero via email tech@eurofins.com

Per qualsiasi chiarimento potrete contattare il nostro Sales Manager, Davide Magistrati (Mob. +39 348.877.22.03), ovvero il Customer Service, Alessia Giaccheri (Tel. 011.22.22.225)
Cordiali saluti.

Eurofins Product Testing Italy Srl
Customer Service Manager



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Eurofins Product Testing Italy S.r.l.
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