EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate no. 123/MDR

On the basis of the assessment carried out according to the Annex IX chapters I and III of the Regulation (EU) 2017/745, we hereby certify that the full quality management system established, documented and implemented:

by the Manufacturer: **MATERIAL CLINICO Y SANITARIO S.L. (MACLYSA S.L.)**

13420 MALAGÓN (CIUDAD REAL) - C/ MURCIA, 69 (POLÍGONO INDUSTRIAL "LAS VIÑAS") (ESP) - Spain

SRN: ES-MF-000016772

for the following devices:

Tubes for oxygen therapy

complies and ensures the compliance of such devices with the applicable requirements of the aforementioned EU Regulation.
The validity of this certificate is subject to the performance of surveillance activities by the Notified Body in accordance with section 3 of the aforementioned Annex.

Further details are indicated in the Technical Attachment which is integral and substantial part of this certificate.

This EU Certificate is issued by IMQ S.p.A. as Notified Body no. 0051 for the Regulation (EU) 2017/745 related to medical devices.

Examinations and tests performed (references to applied common specifications and/or standard included) are documented in the relevant IMQ's conformity assessment Report, traceable through the IMQ's Project (indicated in the section "Revision history" below) and available on request.

First issue date: 2025-11-06

Expiry Date: 2030-11-05

IMQ

This EU certificate is subjected to the provisions laid down by IMQ in the "Regulation for the conformity assessment of medical devices according to Regulation (EU) 2017/745 for which IMQ acts as Notified Body no. 0051". **This is a translation of the Italian text, which prevails in case of doubts**

IMQ S.p.A. | I-20138 Milano | Via Quintiliano 43 | www.imq.it