



EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate no. 008/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:

EURONDA SPA

36030 MONTECCHIO PRECALCINO (VI) - VIA DELL'ARTIGIANATO 7 (ITA) - Italy

SRN: IT-MF-000007762

for the following devices:

Saliva ejector for dental aspirator devices

Steam sterilizing units for medical purpose

Aspirator tips and adapters for dental aspirator devices

Single use instant ice

Sterile devices for infection prevention

Washer-disinfectors employing thermal disinfection, for medical purpose

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.

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IMQ