SUD





EC Certificate

Full Quality Assurance System Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) (Devices in Class IIa, IIb or III)

No. G1 041151 0014 Rev. 00

Manufacturer:

AT-OS S.r.l.

Viale del Lavoro 19

37030 Colognola ai Colli (VR)

ITALY

Facility(ies):

AT-OS S.r.I.

Viale del Lavoro 19, 37030 Colognola ai Colli (VR), ITALY

Product Category(ies): Washer-disinfectors for

non active medical devices

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

ITA1339913

Valid from:

2019-08-27

Valid until:

2024-05-26

Date,

2019-08-27

Stefan Preiß

1. Punil

Head of Certification/Notified Body



Add value. Inspire trust.

TÜV SÜD Product Service GmbH- Ridlerstr. 65 · 80339 Munich · Germany

AT-OS S.r.l. Viale del Lavoro 19 37030 COLOGNOLA AI COLLI (VR) ITALY

 Your reference/letter of
 Our reference/name
 Tel. extension/Email
 Fax extension
 Date
 Page

 041151
 713294212
 +39 3489010334
 2024-03-19
 1 of 23

 ITA1992645_CL
 Paolo.Bolelli@tuvsud.com

TÜV SÜD Product Service GmbH Confirmation Letter CL 041151 0015 Rev. 00

Reference: 713294212

To whom it may concern,

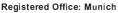
Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have 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 above stated manufacturer with the following SRN Number:

SRN Number: IT-MF-000028623

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 TÜV SÜD Product Service GmbH 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 TÜV SÜD Product Service GmbH has <u>not</u> yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.







If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or 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/AIMDD 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.

The transition timelines in accordance Article 120 (3) of MDR 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, 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 (except 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, 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)

The issuance of the first confirmation letter is free of charge. We reserve the right to invoice further copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=cert:CL-041151-0015-Rev.00

In case of inquiries please contact medical devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH, 2024-03-19

TÜV SÜD Product Service GmbH Medical and Health Services

Paolo Bolelli

Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH Medical and Health Services

Michael Mauermeir (Mar 19, 2024 09:51 GMT+1)

Michael Mauermeir Application Reviewer