



DECLARATION OF CONFORMITY

Manufacturer **AT-OS S.r.l.**
Address **Viale del Lavoro, 19 - Colognola ai Colli (VR) - ITALY**
Product **Machine for washing and disinfection - AWD655**
GMDN Code **35424**
Model Codes **AWD655-8; AWD655-8L; AWD655-8L-SC ; AWD655-10 ; AWD655-10-SC;
AWD655-10D ; AWD655-10D-SC; AWD655-10A; AWD655- 10A-SC;
AWD655-10AD ; AWD655-10AD-SC ; AWD655-15A; AWD655-15A-SC ;
AWD655-15AD ; AWD655-15AD-SC.**

Classification (MDD, Annex IX, rule 15): **IIB**

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentation's are retained under the premises of the manufacturer and the notified body

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE of 14 June 1993 concerning medical devices (MDD 93/42/EEC), Annex I; 2007/47/EEC: updating to the Medical Device Directive 93/42/EEC.

Standards

Standards applicable to this product are:

EN ISO 13485:2016 ; DIN EN 1717:2001 ; EN 61010-1:2010; EN 61010-2-040:2015;
EN 61326-1:2006 + Recommendation NB-MED/2.12 Rec1; EN ISO 15883-1:2009; EN ISO 15883-2:2009.

Notified Body: **TÜV SÜD Product Service GmbH, Ridlerstr. 65,
D- 80339 München, Germany - Id code: 0123**

Conformity Assessment Route: Annex II.3.

Colognola ai Colli, 12.05.2023

AT-OS S.r.l.

Francesco Avesani
(Regulatory Office)