



DECLARATION OF CONFORMITY

Manufacturer	AT-OS S.r.l.
Address (Legal)	Viale Del Lavoro, 19 - Colognola ai Colli (VR) - ITALIA
SRN	IT-MF-000028623
Product:	Endoscope cabinet - ENDO 3
Versions:	ENDO 3, ENDO 3D
Basic UDI-DI:	805673649ENDO3G2
Intended use:	Cabinet for storage of endoscopes
Risk class:	(MDR, Annex VIII, rule 13) : I
EMDN / CND Code :	Z12029099
GMDN Code:	10526

The present EU declaration of conformity has been issued under the sole responsibility of the manufacturer

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the following EU Regulations , Council Directives and Standards. All the documentation is available at the manufacturer.

REGULATIONS AND STANDARDS

Regulations:

MDR Regulation (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices.

Standards

Standards applicable to this product are:

EN ISO 13485:2016; IEC 61010-1:2010; IEC 61326-1:2012; EN 16442:2015.

Common Specifications:

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Conformity Assessment Route: Annexes I, II, III (MDR EU/2017/745).

Colognola ai Colli, 14.04.2023

AT-OS S.r.l.

Francesco Avesani

(Regulatory Affairs)

Declaration signed in the name and on behalf of Mr. Paolo Lorenzini (CEO).