

DECLARATION OF CONFORMITY UE - MD

MANUFACTURER: 	UGOLINI & C. SRL Via L. Da Vinci 58/1 - 50028 Barberino Tavarnelle (FI) Italy e-mail: info@ugolini.it sito web: www.ugolini.it
Unique registration numberof the manufacturer ID/SRN:	IT-MF-00026122

The undersigned Ugolini & c. SRL with registered office in Via L. da Vinci 58/1 50028 Barberino Tavarnelle Italy, share capital 1.000.000 euro (fully paid up) VAT number 03547350482 R.E.A. FI-370905, under its own and sole responsibility, as the manufacturer of the devices in question

DECLARES

that the group of Medical Devices described below complies with the provisions of the EU REGULATION 2017/745 (MDR) and complies with the general safety and performance requirements (Annex I) and the applicable technical standards, reported in the technical file (EN 455 1, 2,3 & 4).

The Technical File containing the relevant documentation is drawn up in accordance with Annex II and is kept at the Manufacturer and made available to the Competent Authorities.

The Manufacturer has implemented and maintains a procedure for after-sales surveillance in agreement in Annex III.

Medical device (MD):	Family: Sanitation system IMPERA Sub-family : Impera 6060 – 1230 – 6030 -3030
	Codice/i (Code): 0M90050002080 - 0MC0060002232 - 0MD0060002231 - 0MG0050002356
UDI-DI di base:	805979677IMPERANUVFV / GS1
Classification:	Annex VIII Chapter 1 – 1.3 Chapter III – 4.1 MDR (REGULATION (EU) 2017/745 on medical devices)

Place, date

Barberino Tavarnelle , 02/08/2022

Legal Representative signature


Ugolini Umberto