



EU DECLARATION OF CONFORMITY

We, undersigned GIMA S.p.A. (single registration number (SRN): IT-MF-000011004), with operational headquarters in Gessate (MI), Via Marconi 1, and registered office in Milan, Via Tommaso Grossi 2, acting as manufacturer of the medical device:

Product and trade name	Product code	Basic UDI-DI
PINARD STETHOSCOPE - aluminium	32505	8023279000U1090995600020L3
WAN PLUS PEDIATRIC DUAL HEAD STETHO - Y black	32506	80232790000C900526BB000N3
WAN NEONATAL STETHOSCOPE - red	32508	80232790000C900527AA000MW
WAN NEONATAL STETHOSCOPE - grey	32509	80232790000C900527AA000MW
WAN PLUS PEDIATRIC DUAL HEAD STETHO - Y pink	32511	80232790000C900526BB000N3
CLASSIC PAEDIATRIC DUAL HEAD STETHO - Y light blue	32512	80232790000C900526BB000N3
WAN PEDIATRIC DUAL HEAD STETHO - Y light blue	32513	80232790000C900526BB000N3
WAN PEDIATRIC DUAL HEAD STETHO - Y red	32515	80232790000C900526BB000N3
CLASSIC PAEDIATRIC DUAL HEAD STETHO - Y black	32516	80232790000C900526BB000N3
LINUX STETHOSCOPE - Y blue	32518	80232790000C900556CC000Q8
LINUX STETHOSCOPE - Y black	32524	80232790000C900556CC000Q8
REGALITE STETHOSCOPE - customized	32525	80232790000C90052700000CW
REGALITE STETHOSCOPE - Y black	32526	80232790000C900527CC000P2
LINUX STETHOSCOPE - Y red	32529	80232790000C900556CC000Q8
CLASSIC DUAL HEAD STETHO - Y dark green	32531	80232790000C900526CC000NM
CLASSIC DUAL HEAD STETHO - Y orange	32532	80232790000C900526CC000NM
CLASSIC DUAL HEAD STETHO - Y light blue	32533	80232790000C900526CC000NM
CLASSIC DUAL HEAD STETHO - Y black	32534	80232790000C900526CC000NM
CLASSIC DUAL HEAD STETHO - Y burgundy	32535	80232790000C900526CC000NM
CLASSIC DUAL HEAD STETHO - Y blue	32536	80232790000C900526CC000NM
CLASSIC DUAL HEAD STETHO - Y green	32537	80232790000C900526CC000NM
CLASSIC DUAL HEAD STETHO - Y red	32538	80232790000C900526CC000NM
CLASSIC DUAL HEAD STETHO - Y pink	32539	80232790000C900526CC000NM
CLASSIC DUAL HEAD STETHO - Y royal blue	32540	80232790000C900526CC000NM
CLASSIC DUAL HEAD STETHO - Y lille	32541	80232790000C900526CC000NM
TEACHING STETHO	32542	80232790000C900526CC000NM
CLASSIC CARDIOLOGY STETHOSCOPE - Y blue	32550	80232790000C90052602000CX
CLASSIC CARDIOLOGY STETHOSCOPE - Y burgundy	32551	80232790000C90052602000CX
CLASSIC CARDIOLOGY STETHOSCOPE - Y black	32552	80232790000C90052602000CX
TRAD DUAL HEAD PEDIATRIC STETHOSCOPE - Y black	32555	80232790000C900526BB000N3
TRAD PEDIATRIC STETHOSCOPE - Y pink	32557	80232790000C900527BB000NG
TRAD STETHOSCOPE - Y dark green	32558	80232790000C900527CC000P2
TRAD PEDIATRIC STETHOSCOPE - Y light blue	32559	80232790000C900527BB000NG
TRAD STETHOSCOPE - Y black	32560	80232790000C900527CC000P2
TRAD STETHOSCOPE - Y red	32561	80232790000C900527CC000P2
TRAD STETHOSCOPE - Y blue	32562	80232790000C900527CC000P2

TRAD STETHOSCOPE - Y yellow	32563	80232790000C900527CC000P2
TRAD STETHOSCOPE - Y purple	32564	80232790000C900527CC000P2
TRAD DUAL HEAD STETHOSCOPE - Y black	32565	80232790000C900526CC000NM
TRAD DUAL HEAD STETHOSCOPE - Y red	32566	80232790000C900526CC000NM
TRAD DUAL HEAD STETHOSCOPE - Y blue	32567	80232790000C900526CC000NM
TRAD DUAL HEAD STETHOSCOPE - Y dark green	32568	80232790000C900526CC000NM
WAN STETHOSCOPE - Y black	32569	80232790000C900527CC000P2
WAN STETHOSCOPE - Y blue	32570	80232790000C900527CC000P2
WAN STETHOSCOPE - Y burgundy	32571	80232790000C900527CC000P2
WAN STETHOSCOPE - Y orange	32572	80232790000C900527CC000P2
WAN DUAL HEAD STETHOSCOPE - Y black	32574	80232790000C900526CC000NM
WAN DUAL HEAD STETHOSCOPE - Y blue	32575	80232790000C900526CC000NM
WAN DUAL HEAD STETHOSCOPE - Y burgundy	32576	80232790000C900526CC000NM
WAN DUAL HEAD STETHOSCOPE - Y orange	32577	80232790000C900526CC000NM
JOTARAP DUAL HEAD STETHOSCOPE - Y purple	32579	80232790000C900526CC000NM
JOTARAP DUAL HEAD STETHOSCOPE - Y black	32580	80232790000C900526CC000NM
JOTARAP DUAL HEAD STETHOSCOPE - Y blue	32581	80232790000C900526CC000NM
JOTARAP DUAL HEAD STETHOSCOPE - Y orange	32582	80232790000C900526CC000NM
JOTARAP DUAL HEAD STETHOSCOPE - Y green	32583	80232790000C900526CC000NM
JOTARAP DUAL HEAD STETHOSCOPE - Y yellow	32584	80232790000C900526CC000NM
JOTARAP DUAL HEAD STETHOSCOPE - Y light blue	32585	80232790000C900526CC000NM
JOTARAP DUAL HEAD STETHOSCOPE - Y fucsia	32586	80232790000C900526CC000NM
JOTARAP DUAL HEAD STETHOSCOPE - Y transparent pink	32587	80232790000C900526CC000NM
YTON NURSE STETHOSCOPE - Y dark green	49500	80232790000C90052700000CW
YTON NURSE STETHOSCOPE - Y dark blue	49501	80232790000C90052700000CW
YTON NURSE STETHOSCOPE - Y red	49502	80232790000C90052700000CW
YTON NURSE STETHOSCOPE - Y aqua blue	49503	80232790000C90052700000CW
YTON DUAL HEAD STETHOSCOPE - Y dark green	49510	80232790000C90052600000CH
YTON DUAL HEAD STETHOSCOPE - Y dark blue	49511	80232790000C90052600000CH
YTON DUAL HEAD STETHOSCOPE - Y red	49512	80232790000C90052600000CH
YTON DUAL HEAD STETHOSCOPE - Y aqua blue	49513	80232790000C90052600000CH
EVOLVE DUAL HEAD STETHO - shiny head - Y black	49550	80232790000C90052600000CH
EVOLVE DUAL HEAD STETHO - shiny head - Y navy black	49551	80232790000C90052600000CH
EVOLVE DUAL HEAD STETHO - shiny head - Y burgundy	49552	80232790000C90052600000CH
EVOLVE DUAL HEAD STETHO - shiny head - Y turquoise	49553	80232790000C90052600000CH
EVOLVE DUAL HEAD STETHO - shiny head - Y grey	49554	80232790000C90052600000CH
EVOLVE DUAL HEAD STETHO - shiny head - Y dark green	49555	80232790000C90052600000CH
EVOLVE DUAL HEAD STETHO - shiny head - Y red	49556	80232790000C90052600000CH
EVOLVE DUAL HEAD STETHO - shiny head - glittered Y ceil blue	49563	80232790000C90052600000CH



EVOLVE DUAL HEAD STETHO - shiny head - glittered Y teal green	49564	80232790000C90052600000CH
EVOLVE DUAL HEAD STETHO - all black head - Y black	49567	80232790000C90052600000CH
EVOLVE DUAL HEAD STETHO - all black head - Y caribbean blue	49568	80232790000C90052600000CH
EVOLVE DUAL HEAD STETHO - all black head - Y emerald green	49569	80232790000C90052600000CH
EVOLVE DUAL HEAD STETHO - all black head - Y chocolate	49570	80232790000C90052600000CH
EVOLVE DUAL HEAD STETHO - multicolour head - Y raspberry	49574	80232790000C90052600000CH
EVOLVE DUAL HEAD STETHO - multicolour head - Y black	49575	80232790000C90052600000CH
EVOLVE DUAL HEAD STETHO - rose gold head - Y white	49578	80232790000C90052600000CH
COLOURED TRAD STETHOSCOPE - black	51000	80232790000C900527CC000P2
COLOURED TRAD STETHOSCOPE - red	51001	80232790000C900527CC000P2
COLOURED TRAD STETHOSCOPE - blue	51002	80232790000C900527CC000P2
COLOURED TRAD STETHOSCOPE - yellow	51003	80232790000C900527CC000P2
COLOURED TRAD STETHOSCOPE - green	51004	80232790000C900527CC000P2
COLOURED TRAD DUAL HEAD STETHOSCOPE - black	51010	80232790000C900526CC000NM
COLOURED TRAD DUAL HEAD STETHOSCOPE - red	51011	80232790000C900526CC000NM
COLOURED TRAD DUAL HEAD STETHOSCOPE - blue	51012	80232790000C900526CC000NM

intended purpose: Intended to allow auscultation of the thorax (heart and lungs) and viscera so that the medical specialist can evaluate certain functions and activities of the human body, in order to diagnose any pathologies,

risk class I (not sterile), in accordance with the rule 1 set out in Annex VIII of the Regulation (EU) 2017/745 (MDR), declares, under its sole responsibility, that this device:

- complies with the Regulation (EU) 2017/745 (MDR);
- Common Specifications have not been used for the compliance of the above medical device.

Gessate, 17/10/2025

GIMA S.p.A.
The legal Representative
(Nicola Manzoni)