

EU DECLARATION OF CONFORMITY
MDR 2017/745

TITANOX S.r.l.

Via Canove de' Biazzi - 26038 TORRE DE' PICENARDI (CR) - Tel: 0375394065

E-mail: info@titanox.it - SRN: IT-MF-000020325

Hereby declare under their own responsibility that

MEDICAL DEVICES CALLED
" BOXES FOR STERILISATION",

Subfamily	Basic UDI-DI	Model
Aluminium boxes	805930470A05SCATALL32	[See below]
Stainless steel boxes	805930470A05SCATINOXQC	[See below]
Instrument tray	805930470A05BACPTAFERYU	[See below]

MANUFACTURED BY TITANOX S.R.L.,

ARE COMPLIANT WITH THE ESSENTIAL SAFETY AND PERFORMANCE
REQUIREMENTS SET FORTH IN ANNEX I OF THE MEDICAL DEVICES
REGULATION 2017/745.

such medical device is complying with all the applicable requirements of the Medical Devices Regulation 2017/745, in particular:

- That the medical device above belongs to Class I, according to Annex VIII of the Medical Devices Regulation 2017/745, rule 1;
- That the medical device above HAS NO MEASURING FUNCTION;
- That the medical device above IS NOT TO BE USED FOR CLINICAL INVESTIGATION;
- That the medical device above IS NOT MARKETING IN A STERILIZED PACKAGE;

Torre de' Picenardi 03.10.2022

(place and date of issue)

Sole Administrator
Enrico Busatti

(name and signature or stamping of the authorized person)

Annex list of devices covered by this declaration

Aluminium boxes	
Code	Description
A1-110-255	ALUMINIUM BOX 25X10X5
A1-111-257	ALUMINIUM BOX 25X10X7
A1-112-256	ALUMINIUM BOX 25X15X6
A1-113-307	ALUMINIUM BOX 30X15X7
A1-114-348	ALUMINIUM BOX 34X20X8
A1-115-357	ALUMINIUM BOX 35X15X7
A1-116-409	ALUMINIUM BOX 40X20X9
A1-117-410	ALUMINIUM BOX 40X30X10
A1-118-428	ALUMINIUM BOX 42X20X8
A1-119-618	ALUMINIUM BOX 61X18X8
Stainless steel boxes	
Code	Description
A1-120-006	BOX FOR STERILIZING GLOVES 30X15X6
A1-121-009	BOX FOR STERILIZING GLOVES 30X15X9
A2-168-180	SMOOTH BOX W/HANDLE 180X80X40 MM
A2-169-200	SMOOTH BOX W/HANDLE 200X100X50 MM
A2-170-220	SMOOTH BOX W/HANDLE 220X120X60 MM
A2-171-250	SMOOTH BOX W/HANDLE 250X120X60 MM
A2-172-300	SMOOTH BOX W/HANDLE 300X120X60 MM
A2-173-320	SMOOTH BOX W/HANDLE 320X150X60 MM
A2-174-400	SMOOTH BOX W/HANDLE 400X160X75 MM
A2-175-500	SMOOTH BOX W/HANDLE 500X200X120 MM
A2-181-180	SMOOTH BOX 180X80X40 MM
A2-181-180/G	SMOOTH BOX 180X80X30 MM
A2-182-200	SMOOTH BOX 200X100X50 MM
A2-182-200/G	SMOOTH BOX 200X100X30 MM
A2-183-220	SMOOTH BOX 220X120X60 MM
A2-184-250	SMOOTH BOX 250X120X60 MM
A2-185-300	SMOOTH BOX 300X120X60 MM
A2-186-320	SMOOTH BOX 320X150X60 MM
A2-187-400	SMOOTH BOX 400X160X75 MM
A2-188-500	SMOOTH BOX 500X200X120 MM
A2-191-180	SMOOTH BOX W/SUPPORT 180X80X40 MM
A2-192-200	SMOOTH BOX W/SUPPORT 200X100X50 MM
A2-193-220	SMOOTH BOX W/SUPPORT 220X120X60 MM
A2-194-250	SMOOTH BOX W/SUPPORT 250X120X60 MM
A2-195-300	SMOOTH BOX W/SUPPORT 300X120X60 MM
A2-196-320	SMOOTH BOX W/SUPPORT 320X150X60 MM
A2-197-400	SMOOTH BOX W/SUPPORT 400X160X75 MM
A2-198-500	SMOOTH BOX W/SUPPORT 500X200X120 MM
Instrument tray	
Code	Description
A2-127-21C	INSTR. TRAY W/LID COMPLETE 210X110 MM
A2-127-21S	INSTR. TRAY W/O INT. TRAY 210X110 MM
A2-128-24C	INSTR. TRAY W/LID COMPLETE 240X160 MM
A2-128-24S	INSTR. TRAY W/O INT. TRAY 240X160 MM
A2-129-30C	INSTR. TRAY W/LID COMPLETE 300X180 MM
A2-129-30S	INSTR. TRAY W/O INT. TRAY 300X180 MM
A2-130-36C	INSTR. TRAY W/LID COMPLETE 360X210 MM
A2-130-36S	INSTR. TRAY W/O INT. TRAY 360X210 MM

A2-131-40C	INSTR. TRAY W/LID COMPLETE 400X230 MM
A2-131-40S	INSTR. TRAY W/O INT. TRAY 400X230 MM
A2-135-210	INSTRUMENT TRAY 21X11X5
A2-136-240	INSTRUMENT TRAY 24X16X5
A2-137-300	INSTRUMENT TRAY 30X18X6,5
A2-138-360	INSTRUMENT TRAY 36X21X7
A2-139-400	INSTRUMENT TRAY 40X23X8