UE 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

UE DECLARATION OF CONFORMITY OF THE MEDICAL DEVICE
"MAYO INSTRUMENT TABLE AND ANAESTHESIA TROLLEY",
MANUFACTURED BY TITANOX S.r.l., WITH THE ESSENTIAL SAFETY AND
PERFORMANCE REQUIREMENTS SET FORTH IN ANNEX I OF THE MEDICAL
DEVICES REGULATION 2017/745.

BASIC UDI-DI: 805930470M02GW

The undersigned TITANOX S.r.l., manufacturer of the medical devices here enclosed

hereby declare under their own responsibility that such medical device is complying with all the applicable requirements of the Medical Devices Regulation 2017/745.

The undersigned declare:

- That the medical device above complies with the Essential Safety and Performance Requirements list in Annex I of the Medical Devices Regulation 2017/745;
- 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;

The undersigned declare that a systematic procedure has been instigate and kept up to date to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions, taking account of the nature and risks in relation to the product.

The undersigned shall make the documentation required by Annex II and III of the Medical Devices Regulation 2017/745, including the declaration of conformity; available to the National Authorities for inspection purposes for a period ending at least ten years after the last product has been manufactured.

Torre de' Picenardi 26 may 2021

Sole Amunistrator
Enrice Busatti

(place and date of issue)

(name and signature or stamping of the authorized person)

Annex list of devices covered by this declaration.

	UE DECLARATION OF CONFORMITY	
TITANOX S.r.l.	MDR 2017/745	
	Mayo instrument table and Anesthesia trolley	

Codice	Descrizione
M600480	MAYO TABLE, WITH 5 CASTORS
M600481	MAYO TABLE S.S. "U" BASE WITH CASTORS
M600482	MAYO TABLE, S.S. BASE, W/CAST. DIM. 62X44
M600485	HYDRAULIQUE MAYO TABLE, W/CASTORS
M600490	ANAESTHESIA TROLLEY