

CE DECLARATION OF CONFORMITY
93/42/EEC

TITANOX S.r.l.
Via Canove, 2/A – Loc. CANOVE DE' BIAZZI
26038 TORRE DE' PICENARDI (CR) - ITALY

CE DECLARATION OF CONFORMITY OF THE MEDICAL DEVICE
"DRY HEAT STERILIZING UNIT" MANUFACTURED BY TITANOX S.R.L, WITH THE
ESSENTIAL REQUIREMENTS SET FORTH IN ANNEX I OF THE MEDICAL DEVICES
DIRECTIVE 93/42/EEC.

The undersigned TITANOX S.r.l., based in Torre de' Picenardi (CR) Italy, manufacturer of the above mentioned medical device, *do hereby declare under their own responsibility that such medical device is complying with all the applicable requirements of the Medical Devices Directive 93/42/EEC.*

The undersigned declare:

- That the medical device above complies with the Essential Requirements list in Annex I of the Medical Devices Directive 93/42/EEC.
- That the medical device above belongs to Class IIa;
- 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 MARKETED IN A STERILIZED PACKAGE;
- That the medical device above is manufactured according to the Quality Sistem certified by Notified Body 0499 SNCH (Certificate of Assessment N° L 0744081-03).

The undersigned declare that a systematic procedure has been instigated 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 VII of the Medical Devices Directive 93/42/EEC, including the declaration of conformity; available to the National Authorities for inspection purposes for a period ending at least five years after the last product has been manufactured.

Torre de' Picenardi 2013-03-21
(luogo e data di emissione)


Enrico Busatti

(nome e firma o timbratura equivalente della persona
autorizzata)

ENCLOSURE: List of Medical Devices of the present declaration.

Codes	Description
A3-211-300	DRY HEAT STERILIZING UNIT MOD. SMALL 3LT
A3-212-400	DRY HEAT STERILIZING UNIT MOD. SMALL 5LT
A3-213-400	DRY HEAT STERILIZING UNIT MOD. PASTEUR ELECTRIC 20LT
A3-214-535	DRY HEAT STERILIZING UNIT MOD. PASTEUR ELECTRIC 60LT
A3-215-670	DRY HEAT STERILIZING UNIT MOD. PASTEUR ELECTRIC 120LT
A3-213-400V	DRY HEAT STERILIZING UNIT MOD. PASTEUR ELECTRIC FORCED HOT AIR 20 LT
A3-214-535V	DRY HEAT STERILIZING UNIT MOD. PASTEUR ELECTRIC FORCED HOT AIR 60 LT
A3-215-670V	DRY HEAT STERILIZING UNIT MOD. PASTEUR ELECTRIC FORCED HOT AIR 120 LT
A3-216-400	DRY HEAT STERILIZING UNIT MOD. ELECTRONIC 20LT
A3-217-535	DRY HEAT STERILIZING UNIT MOD. ELECTRONIC 60LT
A3-218-670	DRY HEAT STERILIZING UNIT MOD. ELECTRONIC 120LT