

## DECLARATION OF CONFORMITY WITH DIRECTIVE 93/42 EEC FOR MEDICAL PRODUCTS

**DESCRIPTION OF GOODS:** POLYMERIC TANK-CONTAINERS FOR  
DISINFECTION AND PRE-STERILIZATION OF MEDICAL INSTRUMENTS

**MODEL:** EKaDH-0,1/01-"ELAT"; EKpDH-0,1/01-"ELAT"; EDPO-1-01;  
EDPO-3-01; EDPO-5-01; EDPO-10-01; EDPO-10D-01; EDPO-1S; EDPO-3S;  
EDPO-5S

• **MANUFACTURER'S NAME:** JOINT STOCK COMPANY "YELATMA  
INSTRUMENT-MAKING ENTERPRISE"

Polymeric tank-containers for disinfection and pre-sterilization of medical instruments are classified in compliance with European Medical Device Directive 93/42/EEC as I Class Safety medical products.

The present declaration confirms that the tank-containers manufactured according to the technical documentation in compliance with Annex VII 93/42 EEC conform to essential requirements of MDD 93/42 EEC Annex 1 and the relevant standard EN ISO 13485:2012 and are entitled to have an CE mark.

Responsible body in EU: MK Touristenbetreuung & Medtechnik  
76, Theodor-Heuss str. 51149, Cologne, Germany

Technical Director:



Mr. A. Kadyrkov

Yelatma, Russia, the 17<sup>th</sup> of August, 2016