



EU DECLARATION OF CONFORMITY

| Manufacturer name | Optium Medikal Ltd.Sti. | | |
|--|---|------------------------------|---------------|
| Registered address | Körkün Mah. Hidayet Cad. No:23 OĞUZELİ GAZIANTEP TURKEY | | |
| Telephone | +90 850 807 6284 | | |
| Fax | +90 850 807 6284 | | |
| E-mail | info@optium.com.tr | | |
| Brand | optium roughing lives | | |
| Directive | Regulation (EU) 2017/745 on medical devices | | |
| Conformity Assessment | Regulation (EU) 2017/745 on medical devices EK-IV EU DECLARATION OF CONFORMITY (EK II & III) | | |
| Classification of the product as the medical device: | According To Annex VIII of Regulation (EU) 2017/745 on medical devices Class I Other (nonsterile, without measuring function) | | |
| Basic UDI-DI | 868289724900MRGCY | | |
| Products | MODEL | Product Name | UDI-DI Number |
| | INOXY 151 | Autopsy Table | 8682897249001 |
| | INOXY 152 | Autopsy Table with Water Gun | 8682897249018 |
| | INOXY 153 | Mortuary Unit Double | 8682897249025 |
| | INOXY 154 | Mortuary Unit Triple | 8682897249032 |
| | INOXY 157 | Body Trolley | 8682897249773 |
| | INOXY 159 | Corps Concealing Trolley | 8682897249780 |
| Description and function designation: | Stainless steel autopsy tables and mortuary units, and trolleys including all applicable accessories. | | |

WE HEREWITH DECLARE THAT THOSE ABOVE PRODUCTS WITH CE MARKING WHICH ARE MANUFACTURED BY OUR COMPANY ALL COMPLY WITH REGULATION (EU) 2017/745 ON MEDICAL DEVICES, AND REALIZE THEIR EXPECTED USES. ALL CE FILES HAVE BEEN CERTIFIED BY THE COMPANY, CONSEQUENTLY THEIR AUTHENTICITY HAS BEEN QUARANTEED.

Harmonised Standarts

The said products fulfills the requirements of these harmonized technical standards which were used for assessing of conformity

A statement that the declaration of conformity is issued under the responsibility of the manufacturer.

Place, Date of Issue : GAZİANTEP / 12.08.2021 Approved By : Ahmet DAL / General Manager

Stamp and Signature :

