



TOUCHING LIVES



## EC CONFORMITY DECLARATION

Date of issue: 29.01.2019

Conformity declaration issued by:

|   |  |  |
|---|--|--|
| <b>Commercial name</b>                                      | Optium Medikal Ltd.Sti.  |  |
| <b>Registered address</b>                                   | Körkün Mah. Hidayet Cad. No:23 OĞUZELİ GAZİANTEP TURKEY  |  |
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| <b>Brand</b>  |  |  |
| <b>Products</b>   | INOXY 111<br>INOXY 112<br>INOXY 113<br>INOXY 121<br>INOXY 122<br>INOXY 123<br>INOXY 133<br>INOXY 136<br>INOXY 139<br>INOXY 141<br>INOXY 142<br>INOXY 151<br>INOXY 152<br>INOXY 153<br>INOXY 154<br>INOXY 159<br>INOXY 158<br>INOXY 157 | Surgical Scrub Unit, Single, Sensor operated<br>Surgical Scrub Unit, Double, Sensor operated<br>Surgical Scrub Unit, Triple, Sensor operated<br>Surgical Scrub Unit, Single, Knee operated<br>Surgical Scrub Unit, Double, Knee operated<br>Surgical Scrub Unit, Triple, Knee operated<br>Instrument Trolley with drawer<br>Work Table<br>Dressing Trolley<br>Operation Room Cupboard with glass doors<br>Operation Room Cupboard with drawer and cabinet<br>Autopsy Table<br>Autopsy Table with water gun<br>Mortuary Unit Double<br>Mortuary Unit Triple<br>Mortuary Unit 9, Corpses<br>Hydraulic Lifter<br>Mortuary Stretcher |
| <b>Description and function designation:</b>                | Various Stainless Steel Hospital Equipments, including all applicable accessories  |  |
| <b>Classification of the product as the medical device:</b> | Class I nonsterile, without measuring function   |  |

### A) Declaration

I declare that the said products are safe under the conditions of common use in compliance with the instructions and that measures have been taken to ensure the conformity of all the products brought to market with basic requirements of directives related thereto, stated in paragraph B.

### B) Fulfilled technical requirements

These products' characteristics comply with the technical parameters related to it and stated in MDD 93/42/EEC as amended, which stipulates the technical parameters for healthcare products.

### C) Means of assessing conformity

Conformity was assessed by the procedure stated MDD 93/42/EEC, Annex VII

### D) Used standards

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

