# EU DECLARATION OF CONFORMITY

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| **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 TOUCHING 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** | 868432544044OTH2Z |

**Products**

| MODEL | Product Name | UDI-DI Numarası | GMDN |
|---|---|---|---|
| **INOXY 141** | Operation Room Cupboard with Glass Doors | 8684325441193 | |
| **INOXY 142** | Operation Room Cupboard with Drawer and Cabinet | 8684325441209 | |
| **INOXY 144** | Cap and Bonnet Cupboard | 8684325441216 | |
| **INOXY 145** | Endoscopy Cabinet | 8684325441223 | |
| **INOXY 265** | Fixed Shelf System | 8684325441513 | |
| **INOXY 266** | Shelf System Unassembled | 8684325441520 | |

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| **Description and function designation:** | Stainless steel cupboards and shelves intended for use to keeps things and instruments including all applicable accessories. |

WE HEREWITH DECLARE THAT THOSE ABOVE PRODUCTS WITH CE MARKING WHICH ARE MANUFACTURED BY OUR COMPANY ALL COMPLY WITH REGULATİON (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 :

optium MEDİKAL LTD. ŞTİ. Körkün Mah. Hidayet Cad. No: 23/1 OĞUZELİ/GAZİANTEP Tic. Sic. No: 55231 Mersis No: 0644067549100001 OĞUZ V.D. : 644 067 54 91

Digitally signed by Grabazei Alexandru
Date: 2025.03.05 15:32:20 EET
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