




TOUCHING LIVES



EU DECLARATION OF CONFORMITY

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|---|---|---|
| Manufacturer name | Optium Medikal Ltd.Sti. | |
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| Brand |  | |
| 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) | |
| Products | MODEL | Product Name |
| | EXAMY 1 | Examination Couch with Cabinet |
| | EXAMY 2 | Examination Couch with Drawers |
| | EXAMY 3 | Examination Couch with Knockdown Construction |
| | EXAMY 4 | Examination Couch, Electrical Height Adjustment |
| | EXAMY 5 | Examination Couch, Height Adjustable |
| EXAMY 6 | Examination Couch, Foldable | |
| Description and function designation: | Examination couches intended for use in the standard care, 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 :

