

## EU DECLARATION OF CONFORMITY

|   |   |
|---|---|
| <b>Manufacturer name</b>                                    | Optium Medikal Ltd.Sti.   |
| <b>Registered address</b>                                   | Körkün Mah. Hidayet Cad. No:23 OĞUZELİ GAZIANTEP TURKEY   |
| <b>Telephone</b>  | +90 850 807 6284  |
| <b>Fax</b>  | +90 850 807 6284  |
| <b>E-mail</b>   | info@optium.com.tr  |
| <b>Brand</b>  |    |
| <b>Directive</b>  | Regulation (EU) 2017/745 on medical devices   |
| <b>Conformity Assessment</b>                                | Regulation (EU) 2017/745 on medical devices EK-IV EU DECLARATION OF CONFORMITY (EK II & III)                                  |
| <b>Classification of the product as the medical device:</b> | According To Annex VIII of Regulation (EU) 2017/745 on medical devices Class I Other (nonsterile, without measuring function) |

### Products

| REF       | Product Name                      | UDI-DI Number | GMDN Code |
|-----------|-----------------------------------|---------------|-----------|
| MOMENTUM  | Functional Trauma Stretcher       | 8682897248219 | 35892     |
| EMERGEUM  | Functional Emergency Stretcher    | 8682897248455 | 35892     |
| TRAVELLER | Patient Stretcher                 | 8682897248462 | 35892     |
| ST 62     | Hydraulic Patient Stretcher       | 8682897248479 | 35892     |
| ST 72     | Patient Stretcher                 | 8682897248486 | 35892     |
| OT TRANS  | Operating Room Transfer Stretcher | 8682897248493 | 35892     |

**Description and function designation:** Patient transfer stretchers intended for use in the standard care and acute care, including all applicable accessories.

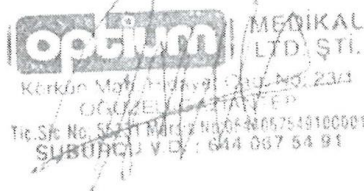
WE HEREWITH DECLARE THAT THOSE ABOVE PRODUCTS WITH CE MARKING WHICH ARE MANUFACTURED BY OUR COMPANY ALL COMPLY WITH REGULATION (EU) 2017/745 ON MEDICAL DEVICES, AND REALIZE THEIR EXPECTED USES. ALL CE FILES HAVE BEEN CERTIFIED BY THE COMPANY, CONSEQUENTLY THEIR AUTHENTICITY HAS BEEN QUARANTEED.

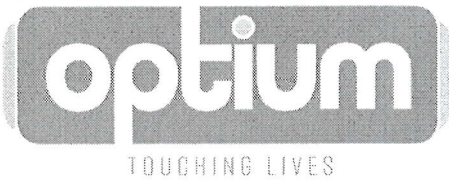
### Harmonised Standarts

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 : GAZIANTEP / 12.08.2021  
Approved By : Ahmet DAL / General Manager  
Stamp and Signature





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|---|---|---|--------------|---------|--------------------------------|---------|--------------------------------|---------|---|---------|---|---------|--------------------------------------|---------|-----------------------------|--|
| <b>Registered address</b>                                   | Körkün Mah. Hidayet Cad. No:23 OĞUZELİ GAZİANTEP TURKEY   |   |              |         |                                |         |                                |         |   |         |   |         |                                      |         |                             |  |
| <b>Telephone</b>  | +90 850 807 6284  |   |              |         |                                |         |                                |         |   |         |   |         |                                      |         |                             |  |
| <b>Fax</b>  | +90 850 807 6284  |   |              |         |                                |         |                                |         |   |         |   |         |                                      |         |                             |  |
| <b>E-mail</b>   | <a href="mailto:info@optium.com.tr">info@optium.com.tr</a>  |   |              |         |                                |         |                                |         |   |         |   |         |                                      |         |                             |  |
| <b>Brand</b>  |    |   |              |         |                                |         |                                |         |   |         |   |         |                                      |         |                             |  |
| <b>Directive</b>  | Regulation (EU) 2017/745 on medical devices   |   |              |         |                                |         |                                |         |   |         |   |         |                                      |         |                             |  |
| <b>Conformity Assessment</b>                                | Regulation (EU) 2017/745 on medical devices EK-IV EU DECLARATION OF CONFORMITY (EK II & III)  |   |              |         |                                |         |                                |         |   |         |   |         |                                      |         |                             |  |
| <b>Classification of the product as the medical device:</b> | According To Annex VIII of Regulation (EU) 2017/745 on medical devices Class I Other (nonsterile, without measuring function)   |   |              |         |                                |         |                                |         |   |         |   |         |                                      |         |                             |  |
| <b>Products</b>   | <table border="1"><thead><tr><th>MODEL</th><th>Product Name</th></tr></thead><tbody><tr><td>EXAMY 1</td><td>Examination Couch with Cabinet</td></tr><tr><td>EXAMY 2</td><td>Examination Couch with Drawers</td></tr><tr><td>EXAMY 3</td><td>Examination Couch with Knockdown Construction</td></tr><tr><td>EXAMY 4</td><td>Examination Couch, Electrical Height Adjustment</td></tr><tr><td>EXAMY 5</td><td>Examination Couch, Height Adjustable</td></tr><tr><td>EXAMY 6</td><td>Examination Couch, Foldable</td></tr></tbody></table> | 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 |  |
|   | 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   |   |              |         |                                |         |                                |         |   |         |   |         |                                      |         |                             |  |
| <b>Description and function designation:</b>                | Examination couches intended for use in the standard care, including all applicable accessories.  |   |              |         |                                |         |                                |         |   |         |   |         |                                      |         |                             |  |

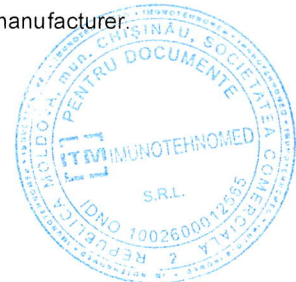
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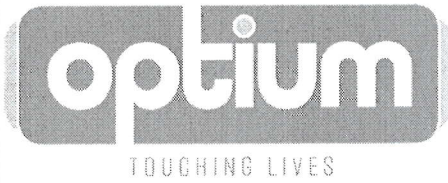
### Harmonised Standarts

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


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





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| <b>Brand</b>  |    |
| <b>Directive</b>  | Regulation (EU) 2017/745 on medical devices   |
| <b>Conformity Assessment</b>                                | Regulation (EU) 2017/745 on medical devices EK-IV EU DECLARATION OF CONFORMITY (EK II & III)                                  |
| <b>Classification of the product as the medical device:</b> | According To Annex VIII of Regulation (EU) 2017/745 on medical devices Class I Other (nonsterile, without measuring function) |
| <b>Basic UDI-DI</b>   | 8682897248011ME7Y   |

|                 | REF   | Product Name                                     | UDI-DI Number | GMDN Code |
|-----------------|-------|--|---------------|-----------|
| <b>Products</b> | ME 55 | Hydraulic ICU and Patient Bed                    | 8682897248233 | 34873     |
|                 | ME 53 | Hydraulic Patient Bed                            | 8682897248240 | 34873     |
|                 | ME 34 | Mechanical Bed, 3 Cranks                         | 8682897248269 | 34873     |
|                 | ME 30 | Manual ICU Bed, 3 Cranks                         | 8682897248257 | 34873     |
|                 | ME 24 | Mechanical Bed, 2 Cranks                         | 8682897248264 | 34873     |
|                 | ME 20 | Manual Patient Care Bed, 2 Cranks                | 8682897248271 | 34873     |
|                 | ME 22 | Manual Patient Care Bed, 2 Cranks, Foldable Legs | 8682897248288 | 34873     |
|                 | ME 11 | Manual Patient Care Bed, 1 Crank, Foldable Legs  | 8682897248295 | 34873     |

|  |  |
|--|--|
| <b>Description and function designation:</b> | Manually operated hospital bed intended for use in the standard care, acute care and intensive care, including all applicable accessories. |
|--|--|

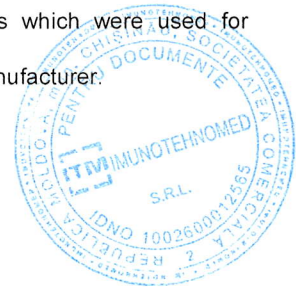
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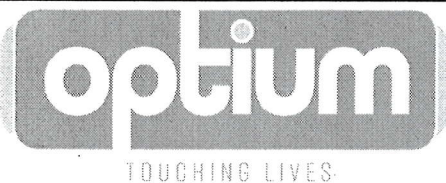
### Harmonised Standarts

The said products fulfills the requirements of these harmonized technical standards which were used for assessing of conformity EN ISO 14971:2012, TS 4271 and EN 60601-2-52:2010

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| <b>Products</b>   | MODEL   | Product Name   |
|   | OP 17   | Folding Screen |
| <b>Description and function designation:</b>                | Hospital furniture equipment including all applicable accessories.  |                |

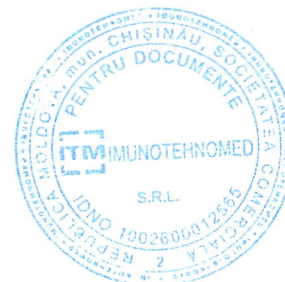
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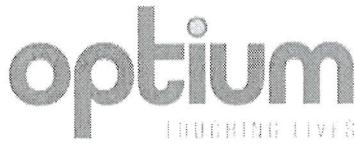
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| <b>Classification of the product as the medical device:</b> | According To Annex VIII of Regulation (EU) 2017/745 on medical devices Class I Other (nonsterile, without measuring function) |
| <b>Basic UDI-DI</b>   | 8682897248011IN86   |

| <b>Products</b> | REF   | Product Name                                  | UDI-DI Number | GMDN Code |
|-----------------|-------|---|---------------|-----------|
|                 | IN-45 | Electronic ICU Bed, Column Motors             | 8682897248004 | 34870     |
|                 | IN-44 | Electronic ICU Bed, Column Motors             | 8682897248011 | 34870     |
|                 | IN-43 | Electronic Low Bed, 4 Motors                  | 8682897248028 | 34870     |
|                 | IN-42 | Electronic ICU Bed, 4 Motors                  | 8682897248035 | 34870     |
|                 | IN-41 | Electronic ICU and Patient Care Bed, 4 Motors | 8682897248042 | 34870     |
|                 | IN-32 | Electronic Patient Care Bed, 3 Motors         | 8682897248059 | 34870     |
|                 | IN-22 | Electronic Patient Care Bed, 2 Motors         | 8682897248066 | 34870     |

**Description and function designation:** Electrically operated hospital bed intended for use in the standard care, acute care and intensive 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 EN ISO 14971:2012, EN 60601-2-38, and EN 60601-2-52:2010

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