




TOUCHING LIVES

EC CONFORMITY DECLARATION

Date of issue: 29.01.2019

Conformity declaration issued by:

Commercial name	Optium Medikal Ltd.Sti.																		
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E-mail	info@optium.com.tr																		
Brand																			
Products	<table><tr><td>STACKER SS</td><td>Stackable Wheelchair, Stainless Steel</td></tr><tr><td>STACKER AL</td><td>Stackable Wheelchair, Aluminum Const.</td></tr><tr><td>STACKER MRI</td><td>Stackable Wheelchair, MRI Compatible</td></tr><tr><td>BD 18</td><td>Blood Drawing Chair</td></tr><tr><td>BD 28</td><td>Blood Drawing Chair, 2 Motors</td></tr><tr><td>BD 48</td><td>Blood Drawing Chair, 4 Motors</td></tr><tr><td>DC 44</td><td>Electronic Dialysis and Chemotherapy Chair, 4 Motors</td></tr><tr><td>SM 08</td><td>Foldable Manual Wheelchair</td></tr><tr><td>SM 09</td><td>Foldable Manual Wheelchair</td></tr></table>	STACKER SS	Stackable Wheelchair, Stainless Steel	STACKER AL	Stackable Wheelchair, Aluminum Const.	STACKER MRI	Stackable Wheelchair, MRI Compatible	BD 18	Blood Drawing Chair	BD 28	Blood Drawing Chair, 2 Motors	BD 48	Blood Drawing Chair, 4 Motors	DC 44	Electronic Dialysis and Chemotherapy Chair, 4 Motors	SM 08	Foldable Manual Wheelchair	SM 09	Foldable Manual Wheelchair
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SM 08	Foldable Manual Wheelchair																		
SM 09	Foldable Manual Wheelchair																		
Description and function designation:	Chairs for transfer patient and blood drawing including all applicable accessories.																		
Classification of the product as the medical device:	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. Directive Regulation (EU) 2017/745 on medical devices

C) Means of assessing conformity

Conformity was assessed by the procedure stated MDD 93/42/EEC and Directive Regulation (EU) 2017/745 on medical devices

D) Used standards

The said products fulfill the requirements of these harmonized technical standards which were used for assessing of conformity: TS 6606 – TS 6607

