



# *EC Declaration of Conformity*

Non-Sterile, Reusable, Fiber Optic Otoscopes

<b>Manufacturers Name:</b>	Gobble Surgical
<b>Manufacturers Address:</b>	Head Marala Road, Gohad Pur, Sialkot, Pakistan
<b>Authorized Representative Name:</b>	Obelis S.A
<b>Authorized Representative Address:</b>	Bd. General Wahis, 53 1030 Brussels, Belgium
<b>Basic UDI-DI:</b>	Awaiting
<b>Name of the Device (s):</b>	Please see next page
<b>Product code:</b>	Please see next page
<b>Classification:</b>	Rule 5, Class I
<b>Notified Body name:</b>	Not Applicable
<b>Notified Body Address:</b>	Not Applicable
<b>Notified Body Identification number:</b>	Not Applicable
<b>Conformity assessment route:</b>	Gobble Surgical uses the following procedures for the CE-labeling of their products according the Regulation MDR 2017/745:

This declaration of conformity is issued under the sole responsibility of Gobble Surgical. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by SGS.

All supporting documentation is retained at the premises of the manufacturer.

Signature:

Place and date of issue:

Ch. M. Saghir

CH. M. SAGHIR  
CEO

Marala Road, Gohad Pur, Sialkot, Pakistan  
24/06/2021



# *EC Declaration of Conformity*

Non-Sterile, Reusable, Fiber Optic Otoscopes

## Product Details for Non-Sterile, Reusable, Fiber Otoscopes

Sr. #	Product Code	Description	UDI-DI Number
1.	0222040010	OTOSCOPE LED BLANC JOLETI	Awaiting
2.	0222040020	OTOSCOPE LED GRIS JOLETI	Awaiting
3.	0222040030	OTOSCOPE LED NOIR JOLETI	Awaiting