EC Declaration of Conformity

Non-Sterile, Reusable, Fiber Optic Otoscopes

Manufacturers Name:	**GOBBLE SURGICAL**
Manufacturers Address:	Head Marala Road, Gohad Pur, Sialkot, Pakistan
Authorized Representative Name:	KB INTERNATIONAL
Authorized Representative Address:	Aurora utca, 13. al. 1, 1084 – Budapest, Hungary
SRN:	PK-MF-000039836
Basic UDI-DI:	Please see next page
Name of the Device (s):	Please see next page
Product code:	Please see next page
Classification:	Rule 5, Class I
Notified Body name:	Not Applicable
Notified Body Address:	Not Applicable
Notified Body Identification number:	Not Applicable
Conformity assessment route:	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 he 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:

Ch. M. Saghir
CH. M. SAGHIR
CEO

Place and date of issue:

Marala Road, Gohad Pur, Sialkot, Pakistan
16/02/2024

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Product Details for Non-Sterile, Reusable, Fiber Otoscopes

Sr. #	Product Code	Description	REFERENCE FOURNISSEUR	UDI-DI Number
1.	0222040010	OTOSCOPE LED BLANC JOLETI		08964003307431
2.	0222040020	OTOSCOPE LED GRIS JOLETI		08964003307448
3.	0222040030	OTOSCOPE LED NOIR JOLETI		08964003307455