bitop AG Carlo-Schmid-Allee 5 44263 Dortmund Germany

Declaration of Conformity

bitop AG
Stockumer Str. 28
58453 Witten, Germany

declares under his sole responsibility that the following medical device

Brand name	**HUMER PHARYNGITE- MIEL CITRON**	
Product Description	**Ectoin containing Lozenges (EHT04)**	
Item number	**33048**	
Contract manufacturer	**Bolder Arzneimittel GmbH & Co.KG**	
Classification	**Class I, rule 5, second indent** (according to Annex IX)	
	UMDNS	**GMDN**
Product category	**Humidifier, moisture exchange**	**Oropharyngeal mucosa protection material, non-sterile**
Product code	**15-645**	**47276**
Lot number	**N/A: Document for registration purpose only**	

Is conforming to the essential requirements listed in **Annex I** of **EC Directive 93/42/EEC** in consideration of the change of the **EC Directive 2007/47/EC**.

This declaration of conformity is based on self-assessment procedure according to **Annex VII** of **EC Directive 93/42/EEC** in consideration of the change of the **EC Directive 2007/47/EC**.
The following standards are applied. The current valid version is summarized in the document ORG-45.

EN ISO 15223-1	EN 1041	EN ISO 10993-1 ff	EN 62366-1
EN ISO 13485	EN ISO 14155	EN ISO 14971	

The above mentioned medical device carries the CE mark: CE

Place and Date of Issue: Dortmund, 02.08.2023

Signature: Majed Bou Malhab
Majed Bou Malhab
2023.08.02 12:56:51
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Senior Regulatory Affairs Manager