

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

<b>Brand name</b>	<b>HUMER PHARYNGITE- MIEL CITRON</b>
<b>Product Description</b>	<b>Ectoin containing Lozenges (EHT04)</b>
<b>Item number</b>	<b>33048</b>
<b>Contract manufacturer</b>	<b>Bolder Arzneimittel GmbH &amp; Co.KG</b>
<b>Classification</b>	<b>Class I, rule 5, second indent (according to Annex IX)</b>

<b>Product category</b>	<b>UMDNS</b> <b>Humidifier, moisture exchange</b>	<b>GMDN</b> <b>Oropharyngeal mucosa protection material, non-sterile</b>
<b>Product code</b>	<b>15-645</b>	<b>47276</b>

**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:



Place and Date of Issue Dortmund, 02.08.2023

Signature

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Senior Regulatory Affairs Manager

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