

bitop AG, Carlo-Schmid-Allee 5, 44283 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>	e.g. Ectoin® Lozenges / Natterman Hoest en Keel Pastilles	
<b>Product family</b>	Ectoin containing Lozenges	
<b>Formulation number</b>	EHT01	
<b>Classification</b>	Class I, rule 5, second indent (according to Annex IX)	
	<b>UMDNS</b>	<b>GMDN</b>
<b>Product category</b>	Humidifier, moisture exchange	Oropharyngeal mucosa protection material, non-sterile  <a href="http://www.gmdnagency.com/TermDetails.aspx?tid=124437">http://www.gmdnagency.com/TermDetails.aspx?tid=124437</a>
<b>Product code</b>	15-645	47276

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	ISO 13408-1 ff
EN ISO 13485	EN ISO 14155	EN ISO 14971	EN 62366

The above mentioned medical device carries the CE mark:



Place and Date of Issue: Witten, 04 July 2018

Signature



Andreas Fink  
 Regulatory Affairs

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bitop AG  
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