

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)

Product category UMDNS Humidifier, moisture exchange GMDN 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:



Place and Date of Issue Dortmund, 02.08.2023

Signature

Senior Regulatory Affairs Manager

bitop AG
Carlo-Schmid-Allee 5, 44263 Dortmund, Germany
Stockumer Straße 28, 58453 Witten, Germany
Fon +49 (0) 231 98 77 44 0, Fax +49 (0) 231 98 77 44 10
office@bitop.de, www.bitop.de

Sparkasse Dortmund (BC 44050199) 741001500
IBAN DE57 4405 0199 0741 0015 00, BIC DORTDE33XXX

Executive Board:
Eva Galik
Wolfgang Hansen

Chairman of the Board:
Dr. Dieter Hahn

bitop AG
registered in Witten

HRB 8147
Local Court of Bochum
VAT No. DE 243 855 091
Tax No. 315/5726/0990