

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	e.g. Ectoin® Ear Spray / Otalgan oorspray 2 in 1	
Product family	Ectoin containing Ear Spray	
Formulation number	EOS01	
Item number	e.g. 30200 / 30604	
Contract manufacturer	Laboratoires Pharmaster	
Classification	Class I, rule 5, second indent (according to Annex IX)	
	UMDNS	GMDN
Product category	Nebulizers	Skin moisture barrier dressing
Product code	12-712	46206
Lot number	LOT / 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	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, 17 April 2018

Signature


Natascha Caroline Teubner
Regulatory Affairs



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