

bitop AG Stockumer Straße 28 58453 Witten Germany

Declaration of Conformity

bitop AG

Stockumer Str. 28
58453 Witten, Germany

declares under his sole responsibility that the following medical device

Brand name	ArdeyEctoin® Ohrenspray	
Product family	Ectoin containing Ear Spray	
Formulation number	E0S01	
Item number	30608	
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	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:

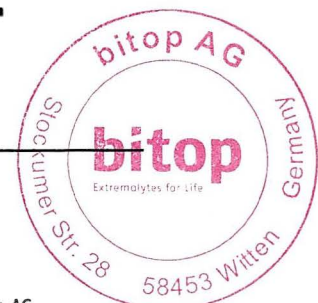


Place and Date of Issue

Witten, 19 January 2021

Signature


Dr. Benjamin Schwartzkopff
Manager Regulatory Affairs



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bitop AG
registered in Witten

HRB 8147
Local Court of Bochum