Declaration of Conformity

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declares under his sole responsibility that the following medical device

Brand name	Hypertonic Saline Nasal Spray this DoC applies also for other brand names/secondary packaging versions of this product family	
Product family	Hypertonic Saline Nasal Spray	
Formulation number	HSNS01	
Item number	6601017 this DoC applies also for other secondary packaging versions of this product family which have a customized article number in the ERP system	
Classification	Class I, rule 5, indent 2 (according to Annex IX)	
	UMDNS	**GMDN**
Product category	Nebulizers	Nasal irrigation saline solution
Product code	12-712	56700
Lot number	This DoC applies for all batches produced during the transition period defined in Article 120, MDR (Regulation (EU) 2017/745) for devices that fulfil the provisions given in this article for legacy devices under EC Directive 93/42/EEC	

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 the EC Directive 93/42/EEC **Annex VII**
The following standards are adopted where applicable. The current valid version is summarized in the document FB 523:

EN 556-2	EN ISO 15223-1	EN 1041	EN ISO 10993-1 ff	IEC 62304-1 ff
EN ISO 13485	EN ISO 14971	EN 62366-1		

The above mentioned medical device carries the CE mark: CE

Tholey, 21.05.2021

Horst Zimmer
General Manager
Head of Quality Management