Declaration of Conformity
Directive 93/42/EEC on Medical Device (MDD)

Legal Manufacturer:	GANSHORN Medizin Electronic GmbH Industriestrasse 6-8, 97618 Niederlauer, Germany
SRN:	**DE-MF-000006566**
QMS:	**Q5 073169 0009**
EC-Certificate:	**G1 073169 0005**
Notified Body:	TÜV SÜD Product Service GmbH, ID 0123 Ridlerstraße 65 80339 München / Munich Germany

Device Information	
Trade Name	**Provo.X**
REF Number	**084200000**
UDI-DI	0 4250972 30016 5 0 7613365 50005 9
Product Type	Nebulizer, non-heated
Intended Purpose	The Provo.X is a device for performing specific and unspecific bronchial provocation tests.
Risk Class according to Annex VIII MDR	IIa
GMDN Code	35457
EMDN Code	Z121590
Basic-UDI-DI	7613365PROVX6V
System Version	Rev. C
Hardware Version	Rev. C
Software Version	Provo.X BL 600 Rev. 1.10
Applied Standard and common specifications	EN ISO 13485:2016 EN 60601-1:2005+A1:2012 EN 60601-1-2:2007 EN 60601-1-6:2010+A1:2013 EN ISO 1041:2013 IEC 62366-1 ISO 15223-1 EN ISO 14971:2022 (ISO 14971:2019) EN ISO 10993-1 EN 13544-1 EN 301 489-1 EN 301 489-17 EN 300 328

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We, the undersigned, declare that the medical device described above is in conformity with the essential requirements of 93/42/EEC (MDD) Annex II excluding (4).

The products are CE marked with notified body number.

CE 0123

RoHS 2 and 3

We, the undersigned, further declare that the medical device described above is in conformity with the applicable provision of the *Directive 2011/65/EU "Restriction of the use of certain hazardous substances in electrical and electronic equipment" and its amended Directive 2015/863/EU.*

This declaration of conformity is issued under the sole responsibility of GANSHORN Medizin Electronic GmbH. This declaration supersedes any declaration issued previously for the same product.

Signed for on behalf of **GANSHORN Medizin Electronic GmbH**

Date of Issue: 2024-02-12

Place of Issue: Niederlauer, Germany

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Name: Sirimanee Chatrojjanasakul

Title / Function: Head of Quality Management and Regulatory Affairs

Signature: [redacted]

Name: Dr. Stefan Ponto

Title / Function: Co-Chief Executive Officer

Sig[redacted]

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Appendix 01 List of compatible medical device(s) and accessories

GANSHORN REF No. as per Label	Accessory / Device name	Legal Manufacturer
019420630	Provo.X Filter	SunMed, LLC (Salter Labs, LLC)
019430012	Provo.X Nebeliser	GVS Filter Technology UK Ltd