


**Gabriel Scientific OÜ**

Declaration of conformity MDR 2017/745

Version 8-05.07.2022

Authorised by: Lyane Lind

**EU declaration of conformity**

<b>Manufacturers Name:</b>	Gabriel Scientific OÜ
<b>Manufacturers Address:</b>	Mauri tee 3, Papsaare küla, Pärnu linn 88317, ESTONIA
<b>SRN (Single Registration Number):</b>	EE-MF-000002642
<b>Basic UDI-DI:</b>	4745010072PneumapureYU
<b>Name of the Device (s):</b>	SleepAngel soft support surfaces (pillows, positioners, duvets, mattresses, top mattresses, wheelchair cushions)
<b>Purpose:</b>	Our patented bedding range is clinically proven to block pathogens, allergens, microbes, and mold. It is the world's first barrier bedding range to combine absolute barrier protection with airflow – for user comfort. Using this advanced technology in the design and manufacture of pillows, mattresses and other cushioning devices, results in a hermetically sealed cushioning device that is a clinically proven barrier to pathogen ingress yet is well ventilated, breathable, and comfortable.
<b>Product number:</b>	301XXXX, 302XXXX, 303XXXX, 305XXXX, 306XXXX, 307XXXX, 308XXXX, 309XXXX, 401XXXX, 402XXXX, 601XXXX Please see Annex I for the detailed list of articles.
<b>Classification:</b>	Class I, Rule 1 according to Annex VIII of Regulation (EU) 2017/745
<b>Conformity assessment Route:</b>	Article 19, Annex II and Annex III according to Regulation (EU) 2017/745.
This declaration of conformity is issued under the sole responsibility of Gabriel Scientific OÜ. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. All supporting documentation is retained at the premises of the manufacturer.	
<b>Signature:</b>  ..... Lyane Lind Head of R&D Member of the Board	<b>Place and date (dd.mm.yyyy) of issue:</b>  Pärnu 28.07.2022 .....