Manufacturer:	Pneumeric, Inc. 823 4th St SW Rochester, MN 55902 United States *SRN:* US-MF-000041677
Authorized Representative:	OMC NI Medical Ltd Unit – 763 Moat House Business Centre 54 Bloomfield Avenue, Belfast Northern Ireland, BT5 5AD

Product:	**Model Number:**	**Basic UDI-DI:**
Capnospot Pneumothorax Decompression Indicator	PDI-001	08600089546PDI-0013V

Risk Classification:	The product listed above is classified as Class I under Rule 1according to Annex VIII of Regulation (EU) 2017/745. No additional rules apply.
Common Specifications:	At the time of the issuance of this declaration, there are no common specifications applicable to the Capnospot device.
Conformity Assessment:	In accordance with Article 52 of Regulation (EU) 2017/745, external conformity assessment is not required. Rather, conformity is declared by issuing this EU DoC after drawing up the necessary technical documentation.

This declaration of conformity is issued under the sole responsibility of Pneumeric, Inc. We hereby declare under our sole authority that the requirements specified in Regulation (EU) 2017/745 have been fulfilled in relation to the above-mentioned product. All relevant supporting documentation is retained by the manufacturer.

Place, Date of Issue of Declaration: Rochester, MN, USA - April, 26th 2024

Signature:

Johnathon M.E. Aho MD PhD. CEO