Adherium (NZ) Limited
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Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	**Address**	**SRN**
Adherium (NZ) Limited	Level 2, 63 Albert Street, Auckland 1010, New Zealand	NZ-MF-000018420 PRRC – Igbal Syre

AUTHORIZED REPRESENTATIVE			
Name of Company	**Address**	**SRN**	**Phone/email**
Emergo Europe	Westervoortsedijk 60; 6827 AT Arnhem; Netherlands	NL-AR-000000116	+31 703 458 570 EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product Name	**Code / Catalog Number**	**Basic UDI-DI**
Hailie® Sensor (for Ventolin® MDI, Flixotide® MDI, Seretide® MDI, ProAir® MDI)	NF0090	942103218NF0090SW
	NF0091	942103218NF0091SY
Hailie® Sensor (for Symbicort® MDI) / pMDI+™	NF0092	942103218NF0092T2
Hailie® Sensor (for Bevespi Aerosphere®) / Bevespi+™	NF0096	942103218NF0096TA
Hailie® Sensor (for Turbuhaler®) / Turbu+™	NF0097	942103218NF0097TC
Hailie® Sensor (for Flixotide®/Seretide® Diskus®/ Accuhaler®)	NF0100	942103218NF0100S8
Hailie® Sensor (for HandiHaler®)	NF0101	942103218NF0101SA
Hailie® Sensor (for Breztri Aerosphere®) / Breztri+™	NF0103	942103218NF0103SE

Intended Purpose	Photo
The Hailie™ sensor is intended for single-patient multiple use as an electronic data capture accessory for monitoring and recording actuations and other parameters, including inspiratory flow, of prescribed inhaler usage. The Hailie™ sensor may be used in the following applications: in clinical practice including trials (where specialists, general practitioners, nurses, and educators	 NF0090 & NF0091  NF0092

need to know if and when a patient has actuated their prescribed medication); and in patient self-management including medication reminders. The Hailie™ sensor is compatible only with the prescribed inhaler. The Hailie™ sensor is not intended to indicate remaining quantity of medication in an inhaler and does not include a dose counting function.	 NF0096  NF0097 & NF0104  NF0100  NF0101  NF0103

RISK CLASS FOR MEDICAL DEVICES		
Device Classification		**Common Specifications / Standards**
Class:	I	• Regulation 2017/745 of 5 April 2017 (as amended) concerning Medical Devices • Directive 2014/53/EU of 16 April 2014 (as amended) concerning Radio Equipment • Directive 2011/65/EU of 8 June 2011 (as amended) concerning Restriction of Hazardous Substances
Rule:	13	

Adherium (NZ) Limited declares that the above-mentioned products meet the provision of the following EU legislation:

Medical Devices Regulation

- *The product classification is Class I according to the* Medical Devices Regulation (EU) 2017/745
- Directive 2014/53/EU of 16 April 2014 (as amended) concerning Radio Equipment, and
- Directive 2011/65/EU of 8 June 2011 (as amended) concerning Restriction of Hazardous Substances (RoHS).

COMPANY REPRESENTATIVE: Igbal Syre
TITLE: Sr. Regulatory Engineer
SIGNATURE:

PLACE: Brisbane, Australia **DATE:** EU format 20/01/2025