Adherium (NZ) Limited
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Declaration of Conformity

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

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

UK RESPONSIBLE PERSON		
Name of company	**Address**	**Telephone/email**
Emergo Consulting (UK) Limited	c/o Cr 360 – UL International Compass House, Vision Park, Histon Cambridge, CB24 9BZ United Kingdom	+44(0) 1223 772 671 UK.Registrations@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
Hailie for Ellipta (for GSK Breo/Relvar, Trelegy, Incruse, Anoro, Arnuity	**NF0106**	942103218NF0106SL

Ellipta)		
Hailie for MDI (short for GSK Advair/Seretide, Flovent/ Flixotide MDI**)**	**NF0107**	942103218NF0107SN
Hailie for MDI (tall for GSK Ventolin MDI**)**	**NF0108**	942103218NF0108SQ
Hailie for Symbicort MDI (for AZ Symbicort MDI)	**NF0109**	942103218NF0109SS

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 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.	   NF0090 & NF0091 NF0092 NF0096    NF0097 NF0100 NF0101    NF0103 NF0106 NF0107   NF0108 NF0109

CONFORMITY ASSESSMENT		
Device classification	**Route to compliance**	**Regulation**
Class I Rule – 12	Part II of the UK MDR 2002, Annex VII	• UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR), • 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).

Adherium (NZ) Limited declares that the above-mentioned products meet the provision of the UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR),

- *The product classification is Class I according to the* Medical Devices Regulation 2002 UK MDR
- 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