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20 January 2025

Manufacturer's Declaration of Conformity for Class I non-sterile, non-measuring, non IVD

Australian Therapeutic Goods (Medical Devices) Regulations 2002 Declaration of Conformity Procedures

This is a declaration of conformity made under Clause 6.6 of Schedule 3 of the **Therapeutic Goods (Medical Devices) Regulations 2002**.

Manufacturer's Name: Adherium (NZ) Ltd
Business Address: Level 2, Albert Street, Auckland 1010, New Zealand

Classification type: Class I non-sterile, non-measuring device
GMDN Code and Term: 61866 Inhaler Dose Sensor
Scope of Application: All Hailie Sensor Family

Standards applied to the device(s)

Standards	ISO 13485, ISO 14971, IEC 60601-1, IEC 60601-1-11, IEC 60601-1-2, EN 300 328, EN 301 489-17 RoSH3, RED

Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles and the classification rules before being supplied.

Name of medical device(s) / IVD(s)

Identify the specific device/s this form relates to for example, the name of the device or model numbers of the device and any variants that are being manufactured for supply in Australia.

Product name	Model/number	GMDN Code
Hailie® Sensor (for Ventolin® MDI, Flixotide® MDI, Seretide® MDI, ProAir® MDI) Hailie® Sensor (for Symbicort® MDI) / pMDI+™	NF0090/ NF0091 NF0092	61866 – Inhaler Dose Counter

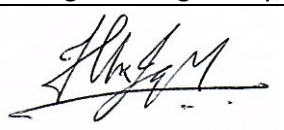
Product name	Model/number	GMDN Code
Hailie® Sensor (for Bevespi Aerosphere®) / Bevespi+™	NF0096	61866 – Inhaler Dose Counter
Hailie® Sensor (for Turbuhaler®) / Turbu+™	NF0097	
Hailie® Sensor (for Flixotide®/Seretide® Diskus®/ Accuhaler®)	NF0100	
Hailie® Sensor (for HandiHaler®)	NF0101	
Hailie® Sensor (for Breztri Aerosphere®) / Breztri+™	NF01013	
Hailie® Sensor (for Ellipta® DPI)	NF0106	
Hailie® Sensor (for GSK pMDI Aerosphere®)	NF0107	
Hailie® Sensor (for GSK pMDI Aerosphere®)	NF0108	
Hailie® Sensor (for Symbicort® pMDI)	NF0109	
Hailie Sensor (for Teva ProAir MDI)	NF0110	

This declaration is being made under clause 6.6 of Schedule 3 to the Regulations for a Class I non-sterile, non-measuring device or Class 1 IVD medical device.

By signing this form you are agreeing that:

- You have reviewed the Declaration of Conformity procedures under Part 6 of Schedule 3 of the Regulations and the device complies with the applicable provisions of those procedures.
- The device complies with the relevant essential principles set out in Schedule 1 to the Regulations.
- The device complies with the applicable provisions of the classification rules set out in Schedule 2 to the Regulations.
- You will update the technical documentation when any changes are made in relation to the device.

Authorised Signatory:

Name	Igbal Syre		
Title	Sr. Engineer Regulatory, Adherium (NZ) Ltd		
Signature		Date	20 January 2025