

	DOC Declaration of Conformity		
Managementsysteem	Valid: 2024-07-01	Version: 1.0	Page 1 of 2

DECLARATION OF CONFORMITY

1 Manufacturer

Company name: Spruyt hillen bv
Address: Venkelbaan 101
2908 KE Capelle aan den IJssel
The Netherlands

SRN (Single Registration Number): NL-MF-000042045

2 Device(s):

	Device group	Basic UDI-DI
1	CountAir®	87171590

See appendix on page 2

3 The device(s) described above is in conformity with:

Title	Document No.
Medical Device Regulation	(EU) 2017/745

4 Additional information:

This declaration of conformity is issued under the sole responsibility of Spruyt hillen BV. 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.

Place Capelle aan den IJssel

Name I. Damen

Date 2024-07-01

Function QA Officer

Signature



Appendix

List of devices

Date: 2024-07-01

Device name	Device code ¹	Intended purpose	Risk class & rule ²
CountAir® Wit luxe verpakking	211220	The CountAir® is a dose counter displaying the number of aerosol doses left in a metered dose inhaler (MDI).	Class I rule 13
CountAir® Blauw luxe verpakking	211221	The CountAir® is a dose counter displaying the number of aerosol doses left in a metered dose inhaler (MDI).	Class I rule 13
CountAir® Wit apo verpakking	211222	The CountAir® is a dose counter displaying the number of aerosol doses left in a metered dose inhaler (MDI).	Class I rule 13
CountAir® Blauw Apo verpakking	221223	The CountAir® is a dose counter displaying the number of aerosol doses left in a metered dose inhaler (MDI).	Class I rule 13
CountAir® Czech republic Wit	211340	The CountAir® is a dose counter displaying the number of aerosol doses left in a metered dose inhaler (MDI).	Class I rule 13
CountAir® Apo verp Noorwegen	211624	The CountAir® is a dose counter displaying the number of aerosol doses left in a metered dose inhaler (MDI).	Class I rule 13
CountAir® Apo verpak Denemarken	211625	The CountAir® is a dose counter displaying the number of aerosol doses left in a metered dose inhaler (MDI).	Class I rule 13
CountAir® Wit Apo verpak UK	211764	The CountAir® is a dose counter displaying the number of aerosol doses left in a metered dose inhaler (MDI).	Class I rule 13
CountAir® Scandinavia	211908	The CountAir® is a dose counter displaying the number of aerosol doses left in a metered dose inhaler (MDI).	Class I rule 13

¹ Device and trade name, device code, catalogue number or other unambiguous reference allowing identification and traceability of the device covered by the EU declaration of conformity, such as a photograph, where appropriate, as well as its intended purpose. Except for the device or trade name, the information allowing identification and traceability may be provided by the Basic UDI-DI

² See risk classification in Medical Device Regulation, annex VIII