Declaration of Conformity to EU Medical Device Regulation 2017/745

Legal Manufacturer	Coloplast A/S Holtedam 1, 3050 Humlebaek, DK SRN: DK-MF-000025526
EU Product Classification according to Annex VIII	I Rule Number: 1, 11, 13
Intended Purpose	The system is intended to be used together with an ostomy baseplate and bag, to detect and notify user of the occurrence of output leakage under an ostomy baseplate.
Basic UDI-DI	5708932118567805N3
Conformity to Common Specification(s)	No relevant Common Specification to list
Conformity to other Union Legislation(s)	Radio Equipment Directive 2014/53/EU Restriction of Hazardous Substances Directive 2011/65/EU

This EU Declaration of Conformity is applicable for following catalogue numbers:

Catalogue Number	Product Name	Original CE Marking Date yyyy-mm-dd
19201	Heylo Starter kit	2021-06-14
19202	Heylo Starter kit	2021-06-14
19203	Heylo Starter kit	2021-06-14
19204	Heylo Starter kit	2021-06-14
19205	Heylo Starter kit	2021-06-14
19210	Heylo Sensor layer	2021-06-14
19211	Heylo Sensor layer	2021-06-14
19212	Heylo Sensor layer	2021-06-14
19213	Heylo Sensor layer	2021-06-14
19214	Heylo Sensor layer	2021-06-14
19240	Heylo Transmitter	2024-09-27
19242	Heylo Charger	2024-09-27

This EU Declaration of Conformity is issued under the sole responsibility of Coloplast A/S. Coloplast A/S declares that the devices covered by the present declaration are in conformity with the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and the requirements specified herein are fulfilled.

The devices that are covered by the present declaration are in conformity with the relevant Union legislation(s) referenced in this declaration.

Date of signature:	2024-11-06
	yyyy-mm-dd
Place of signature:	Humlebaek, Denmark
	Place, Country
	DKBENB, Benedikte Blom, Director of Regulatory Affairs, Chronic Care
Signed on behalf of Coloplast A/S:	
	Name, Title