

**PRODOTTO DA:**

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**MANDATARIO UNICO EUROPEO:**

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**CE DECLARATION OF CONFORMITY****MDR (UE) 2017/745 ANNEX IV**

We hereby declare that compliance with **MDR (EU) 2017/745** has been verified for the medical device. Therefore, the producer declares under his own responsibility that:

- The medical device “**AIRNOTE CEROTTO PROFUMATO PER INCONTINENZA E STOMA**” complies with the general safety and performance requirements set out in **Annex I of MDR (EU) 2017/745**,
- The medical device **AIRNOTE CEROTTO PROFUMATO PER INCONTINENZA E STOMA**, classified as a **Class I** medical device (non-sterile, without measuring functions) according to **Annex VIII of the MDR Directive (EU) 2017/745**,
- For the medical device, **AIRNOTE CEROTTO PROFUMATO PER INCONTINENZA E STOMA** the conformity assessment process was carried out as per **Annex VIII of the MDR Directive (EU) 2017/745**.

On the basis of the evidence collected in terms of CE conformity, the medical device “**AIRNOTE CEROTTO PROFUMATO PER INCONTINENZA E STOMA**” is notified in the database of the Ministry of Health with **RDM 2320790**

Evidence is provided as follows in the notification screen:

PROGRESSIVE SYSTEM ASSIGNED TO THE DEVICE	PRODUCER	CODE ASSIGNED BY THE PRODUCER (CATALOG IDENTIFIER)	TRADE NAME AND MODEL	CND CLASSIFICATION
2320790	AIR NOTE GMBH	AIR NOTE CEROTTO PROFUMATO	AIR NOTE CEROTTO PROFUMATO PER INCONTINENZA & STOMA	T99 – DISPOSITIVI DI PROTEZIONE E AUSILI PER INCONTINENZA (ESCLUSI I DISPOSITIVI DI PROTEZIONE INDIVIDUALE DPI)

Zurich, the 17-10-2022

THE LEGAL REPRESENTATIVE



Nicola Renda

Air Note GmbH