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Mirandola, 14.01.2025

Declaratory Letter

To whom it may concern,

Object: Declaration of conformity – Code list

**Manufacturer (MDR Regulation (EU)
2017/745):**

B. Braun Avitum S.p.A.
Via XXV Luglio, 11
41037 Mirandola (MO)
Italy

Devices concerned

Continence care medical devices:

- Actreen
- Diveen

We, B. Braun Avitum Italy S.p.A., herewith declare that:

The Declaration of Conformity for Continence care (Actreen and Diveen) medical devices contains the full list of codes related to the specific product range.

The suffix, representing the country where the Medical Device article is sold, appears only on the product label and relates to the specific language for each country.

For example: -U suffix is specific for Czech Republic and Slovakia, -D is specific for Spain, -A is undifferentiated suffix with English text.

Independently on the suffixes for different countries, the same root code refers exactly to the same product item.


Chiara Bergamini

Vice President Regulatory Affairs



Martina Pizzetti

Regulatory Affairs Team Leader