COLTENE

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Place, Date:
Altstätten, 09.08.2023

MDD Declaration of Conformity – Reference to EC Representative

To whom it may concern,

Prior to all Coltène/Whaledent AG products being placed on the market under the Medical Device Directive (MDD), a Declaration of Conformity in full compliance with the requirements for Annex II of the MDD was drawn up. The required contents of the Declaration of Conformity at the time did not include reference the EC Representative, and therefore inclusion was not required.

The Medical Device Regulation (MDR) has a much more specific set of requirements than the MDD, set out in Annex IV, which include the requirement to reference the EC Representative, which we do in our MDR compliant Declarations of Conformity.

We can confirm that we meet all requirements relating to EC Representives for both MDD and MDR products – we have appointed an EC Rep, met all local requirements, and include this information on the label.

09.08.2023

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Oliver Ashe
Regulatory Affairs Manager