



Annex I to Declaration of conformity Ceramic burs

Amended documents

EU Declaration of conformity Ceramic burs Rev. E 05.10.2022

Reason of changes

Request from the Customs Authorities (in particular from Italy as well as from Spain) to include the name and address of the Authorised Representative in the declaration of conformity.

Changes made to the documents mentioned

Added address of the European Authorised Representative.

Rationale for changes made to documents.

The Authorised Representative's address has been added to the declarations of conformity.

EU-Representative : Kiron di Mechelli Claudio, Via F. Guglielmino, 55, I-00137 Roma, Italy

It should be noted that the Representative has not changed.

Conclusions

On the basis of the above, we believe that the changes to the Declarations of Conformity are not considered as significant changes as they do not change the design and/or intended use.

This conclusion was also reached by following the indications provided by the MDCG 2020-3 document (guidance to support the assessment of changes in accordance with Article 120(3) of the MDR 2017/745 regulation).

Gordevio 16.01.2024

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