



Annex to Declaration of conformity Carbide burs

Amending document

EU Declaration of conformity Carbide burs Rev. C 07.03.2020

Reason of changes

05.10.2022

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.

10.07.2024

The certification according to EN ISO 13485 has been renewed.

Addendum/Changes to be applied to the document mentioned above

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

Old declaration:

The products have been developed, manufactured and controlled within a Quality System meeting the requirements of EN ISO 13485:2016. Certificate ICIM No. 9662/0, IQNet registration Number IT-116615.

New declaration:

The products have been developed, manufactured, and controlled within a Quality System meeting the requirements of EN ISO 13485:2021, ISO13485:2016.
Certificate No. ICIM-13485-009662-03, IQNet registration Number IT-116615 ICIM-13485-009662-03.

Rationale for changes made to documents.

The Authorised Representative's address has been added to the declarations of conformity.
It should be noted that the Representative has not changed.

In the above-mentioned declaration of conformity, the certificate number and references to standards have been updated.

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 10.07.2024

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