



## Annex II to Declaration of conformity Carbide burs

### Amended documents

EU Declaration of conformity Carbide burs Rev. F 13.11.2023

### Reason of changes

The ICIM Certificate has been reissued according to the new EN ISO 13485:2021 standards and has received a new reference number.

### Changes made to the documents mentioned

Updated references to the ICIM certificate concerning the EN ISO 13485:2021 standard.

### Rationale for changes made to documents.

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 16.01.2024

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