Manufacturer Declaration

Medcem GmbH has a Quality Management System meeting the requirements of the standard EN ISO 13485:2016 in relation to design, manufacture and distribution of medical devices for dentistry.

Our products have the declaration of conformity with the medical device directive 93/42/EEC.

Class IIa products
According to the Regulation (EU) 2023/607 as regards the transitional provision for certain medical devices certificates issued by notified bodies in accordance with the directive 93/42/EEC that were still valid on 26.05.2021 and that have not been withdrawn afterwards shall remain valid after the end of the period indicated on the certificate until the date 31.12.2028 for all IIa class devices. Medcem GmbH meets the requirements of the regulation, therefore certificate Reg. no. 36633 is valid.

Class I products
According to the Regulation (EU) 2023/607, devices for which the conformity assessment procedure pursuant to Directive 93/42/EEC did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body, may be placed on the market or put into service until 31 December 2028.