exocad

Dental implant planning software

exoplan 3.1 Rijeka

Basic UDI-DI 426052136EXOPLAN21A6

EU Declaration of Conformity

Dental implant planning software (class IIa) exoplan meets the provisions of Regulation (EU) 2017/745 on medical devices. The CE marking of conformity applied to this device encompasses all other directives, regulations, and additional Union legislation.

Intended Purpose:

exoplan is a medical software, intended to support the pre-operative planning of dental implants using the visualization of the implant placement within images of the patient's anatomy. The process is based on CT/CBCT data sets originating from other medical devices, and can be supported by optical scan(s) of the patient's anatomy as well as a virtual prosthetic proposal.
exoplan allows the design of surgical guides to support the placement of endosseous dental implants in guided surgery. The design of surgical guides is based on 3D surface data representing the preoperative situation and approved implant positions. Alternatively, instead of optical surface data a second CBCT/CT dataset can be used. The software exports the planning and design results as geometrical data and a digital 3D model of the surgical guide to support the manufacture of a separate physical product.
exoplan does not extend or change indications of dental implants. Usage of a surgical guide designed with the software does not change the necessary due diligence required compared to conventional (non-guided) surgery.
The software is intended to be used only by dental professionals with sufficient medical training in dental implantology and surgical dentistry in office environments suitable for reading diagnostic dental DICOM data sets. exoplan shall not be used for any purpose other than planning dental implant placement or design of surgical guides.

Indications

exoplan is indicated to be used as a medical front-end, pre-operative software program by medically trained persons for simulating/evaluating the placement of implants and surgical treatment options.
The indications of dental implants do not change with guided surgery compared to conventional surgery.

Contraindications

exoplan is not for diagnostic purposes.
exoplan is not intended for edentulous patients in need of bone-supported surgical guide.
exoplan only supports the planning of treatments for adults.
This version of exoplan does not support the planning with implants with an angled prosthetic platform connection, including zygomatic implants.

The device is manufactured by exocad GmbH, who is exclusively responsible for this declaration of conformity.

exocad GmbH has established and maintains a quality management system according to the requirements of Annex IX Chapter I and III of Regulation (EU) 2017/745 under the supervision of the notified body BSI The Netherlands B.V. (CE2797). The conformity of the subject medical device has been assessed as per these requirements. This declaration is bound to the validity of certificates MD 794750 (valid thru 2025-05-01) and MDR 738262 (valid thru 2027-04-07).

No Common Specification applies.

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