

## MDD EXTENSION APPROVAL LETTER

13.10.2023

To whom It May Concern,

As UDEM A.Ş., operating as a notified body within the scope of the 93/42/EEC Medical Device Regulation, we have issued an EC certificate on the date 29/08/2018 within the scope of the 93/42/EEC Medical Device Directive for the company and products whose information is given in Table-1. We declare that the certificate is valid for the products given in Table-1 before the expiry date of the relevant certificate.

**Table-1**

Company Name	EC Certificate No	Scope	Expiry Date
NOTCH IMPLANT GMBH	M.2018.106.10556	Sterile Dental Implant and Closing Screw - Class IIb Non-Sterile Dental Abutment - Class IIb Non-sterile Gingiva and Healing Screw - Class IIb	14.10.2023

In order to confirm the applicability of the provisions regarding the extension of the validity periods of the 93/42/EEC certificates within the scope of the Regulation on the Amendment of the Medical Device Regulation published in the Official Gazette dated 02 April 2023 and numbered 32151, UDFRM.305 Extension Process Information Form On EC Certificates Applicable Under 9342EEC has been provided from the relevant company. When the information provided by the company is reviewed, it has been shared that an application has been made to another notified body authorized under (EU) 2017/745 for the products given in Table-2 within the scope of the said EC certificate and/or the devices intended to replace it and/or a contract has been signed with the relevant notified body.

**Table-2**

Device	MDR NB	Date of Application	Date of Contract
Sterile Dental Implant and Closing Screw - Class IIb Non-Sterile Dental Abutment - Class IIb Non-sterile Gingiva and Healing Screw - Class IIb	2696	12.05.2023	17.05.2023


In accordance with the Regulation Amending the Medical Device Regulation, for the products listed in Table-2, which are within the scope of the EC certificate for the above-mentioned company and are also under the MDR contract, unless undertaken by the other notified body after the MDR contract, we declare that we have undertaken the surveillance audit responsibility until 26 September 2024 with UDFRM.07-2 Additional Contract On Extension Of The Validity Period Of EC Certificates signed by the relevant company and UDEM A.Ş. on 07.10.2023 as specified in Article 120 (3e) of the relevant Regulation. As of 26.05.2024, we do not have any surveillance responsibility for products that are within the scope of EC certificate but do not have an MDR application/contract.

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The execution of the said surveillance audits will continue depending on the company's fulfillment of the obligations set forth in Article 120 (3c) of the relevant Regulation.

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Medical Device Technical Regulation Responsible

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