Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
102917	Jiao Chen	Jiao.chen@tuvsud.com	N/A	2024-04-29	1 of 2

TÜV SÜD Product Service GmbH

Receipt of formal application

Reference: Prima_Bur_01

To whom it may concern,

Confirmation of the status of a formal application in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received **a formal application** in accordance with Section 4.3, first subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: GB-MF-000023281

The devices covered by the formal application mentioned above are identified in the Table below.

Please note that this letter only confirms the status of the formal application.

To benefit from the additional transitional provisions in the framework of Regulation EU 2023/607, TÜV SÜD Product Service GmbH and the manufacturer need to sign a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR latest until 26 September 2024.

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
29th April 2024

TÜV SÜD Product Service GmbH
Medical and Health Services

Jiao Chen

Jiao Chen
Conformity Assessment Responsible (CARE)

Devices covered by the formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR

Device name or Basic UDI-DI (under MDR application)
Device 1 **Carbide Rotary Dental Bur** (Basic UDI-DI: 50560207CARB012V)
Device 2 **Diamond Rotary Dental Bur** (Basic UDI-DI: 50560207DIAM0346)
Device 3 **Steel Rotary Dental Bur** (Basic UDI-DI: 50560207STEE11DM)