Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
053618	ITA1482964425	+39 342 38 62 885 rachele.ruggeri@tuvsud.com		2024-03-19	1 of 3

TÜV SÜD Product Service GmbH

Receipt of formal application

Reference: ITA1482964425

ZHERMACK SPA - Via Bovazecchino 100, I-45021 Badia Polesine (RO), Italy

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: **IT-MF-000011215**

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,
2024-03-19

TÜV SÜD Product Service GmbH
Medical and Health Services

Rachele Ruggeri
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 **C810000 - ZETA 1 ULTRA** **BUDI: 805600037Z0104B**
Device 2 **C810011 - ZETA 2 SPOREX** **BUDI: 805600037Z0204E**
Device 3 **C810023 - ZETA 3 SOFT** **BUDI: 805600037Z0304H**
Device 4 **C810024 - ZETA 3 SOFT** **BUDI: 805600037Z0304H**
Device 5 **C810025 - ZETA 3 FOAM** **BUDI: 805600037Z0314K**
Device 6 **C810026 - ZETA 3 FOAM** **BUDI: 805600037Z0314K**
Device 7 **C810027 - ZETA 3 SOFT** **BUDI: 805600037Z0304H**
Device 8 **C810028 - ZETA 3 SOFT** **BUDI: 805600037Z0304H**
Device 9 **C810029 - ZETA 3 SOFT** **BUDI: 805600037Z0304H**
Device 10 **C810032 - ZETA 3 SOFT** **BUDI: 805600037Z0304H**
Device 11 **C810040 - ZETA 5 POWER ACT** **BUDI: 805600037Z0504P**
Device 12 **C810048 - ZETA 7 SOLUTION** **BUDI: 805600037Z0714X**

Device name or Basic UDI-DI (under MDR application)
Device 13 **C810050 - ZETA 7 SPRAY** **BUDI: 805600037Z0704V**
Device 14 **C810062 - ZETA 3 WIPES TOTAL** **BUDI: 805600037Z0314K**
Device 15 **C810063 - ZETA 3 WIPES TOTAL** **BUDI: 805600037Z0314K**
Device 16 **C700200 - ACRYTEMP CB A2** **BUDI: 805600037ACR04N**
Device 17 **C700201 - ACRYTEMP CB A1** **BUDI: 805600037ACR04N**
Device 18 **C700205- ACRYTEMP CB A 3,5** **BUDI: 805600037ACR04N**
Device 19 **C700211 - ACRYTEMP CB B1** **BUDI: 805600037ACR04N**
Device 20 **C700215 - ACRYTEMP CB A3** **BUDI: 805600037ACR04N**