

Roechling Medical Lancaster  
44 Denver Road  
Denver, USA 17517



## TÜV SÜD Product Service GmbH

Your reference/letter of 83867	Our reference/name <b>1476992131</b>	Tel. extension/Email Soumya.jaganathan@tuvsud.com	Fax extension	Date 05/23/2024	Page 1 of 5
-----------------------------------	---	--	---------------	--------------------	----------------

### **Receipt of formal application**

**Reference: 1476992131**

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: US-MF-000027642

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](mailto:medical_devices@tuvsud.com).

On behalf of the Notified Body TÜV SÜD Product Service GmbH,  
May 23 2024

TÜV SÜD Product Service GmbH  
Medical and Health Services

---

Soumya Jaganathan  
Conformity Assessment Responsible (CARE)

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

Roechling Medical Lancaster  
44 Denver Road  
Denver, USA 17517



Device name	Basic UDI-DI (under MDR application)
Sterile Bifurcated Vaccinating Needle	086865200022CM
Sterile Bifurcated Allergy Skin Testing Needle	086865200020CH