



Zhejiang Kindly Medical Devices Co., Ltd.  
No.758, 5th Binhai Road, Binhai Industrial Park, Longwan District, 325025 Wenzhou, Zhejiang  
Province, PEOPLE'S REPUBLIC OF CHINA

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
036336	BJ-ZKDL-CL	+86-10-6590-6186 <a href="mailto:jinglin.chen@tuvsud.com">jinglin.chen@tuvsud.com</a>	+86-10-6590-6182	2024.05.21	1 of 3

## **TÜV SÜD Product Service GmbH** **Receipt of formal application**

**Reference: BJ-ZKDL-CL**

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: CN-MF-000007594

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,  
2024.05.21



TÜV SÜD Product Service GmbH  
Medical and Health Services

*Jinglin Chen*

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Jinglin 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)
<b>Device 1</b> Sterile syringe
<b>Device 2</b> Extension set
<b>Device 3</b> Stopcock
<b>Device 4</b> Heparin cap
<b>Device 5</b> Huber needle
<b>Device 6</b> Biopsy needle
<b>Device 7</b> Intravascular catheter introducer
<b>Device 8</b> Percutaneous vertebroplasty kit
<b>Device 9</b> Infusion set
<b>Device 10</b> Burette-type infusion set
<b>Device 11</b> Transfusion set
<b>Device 12</b> Syringe