



## Declaration of Conformity

1. Manufacturer: Xuchang Zhende Surgical Dressing Co., Ltd.  
Site 1: No. 1 Jinhui Road, Industry Cluster District, Yanling County, 461200,  
Xuchang City, Henan Province, China  
Site 2(Legal Manufacturer): Area A, Baihua Road East, South Side of Erji river,  
Industry Cluster District, Yanling County 461200 Xuchang, Henan PEOPLE'  
S REPUBLIC OF CHINA
2. EC Representative: Shanghai International Holding Corp. GmbH (Europe)  
Eiffestraße 80, 20537 Hamburg, Germany
3. Product name Procedural Dressing Trays  
Product type: Dressing Tray for Wound care /Dressing change tray  
UMDNS Code: 17168
4. Classification (MDD, Annex IX): IIa, Rule 7  
Conformity Assessment Route: Annex II section 3
5. Statement:  
We herein declare in our own responsibility that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.
6. DIRECTIVES  
General applicable directives:  
Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).
7. Standard Applied: EN ISO 15223-1:2021 EN 14079:2003  
EN ISO 13485:2016 EN ISO 14971:2012
8. Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr, 65, 80339  
München, Germany  
  
NB Identification number: 0123
9. (EC) Certificate(s): G1 109397 0004 Rev.00  
Expire date of the Certificate: 2024-03-03  
Start of CE Marking: 2018-09-30

Signature:

Name: Chen Ming

Date: 2022.05.27

Position: Regulatory Director



## Product List

| No | REF    | ZD Code        | NAME SET ENGLISH                        |
|----|--------|----------------|-----------------------------------------|
| 1  | 145727 | N11000111K-128 | Raucoset® Gauze Balls Set               |
| 2  | 145832 | N11000111K-129 | Raucoset® Suture Set                    |
| 3  | 145329 | N11000111K-130 | Raucoset® Catheter Connector Set        |
| 4  | 145749 | N11000111K-131 | Raucoset® Probe Set                     |
| 5  | 145551 | N11000111K-132 | Raucoset® Vulval Treatment Set          |
| 6  | 145306 | N11000111K-134 | Raucoset® Buttoned Probe                |
| 7  | 145965 | N11000111K-135 | Raucoset® Probe Set without ampoules    |
| 8  | 145499 | N11000111K-136 | Raucoset® Connector Set C               |
| 9  | 145455 | N11000111K-138 | Raucoset® Disinfection Set              |
| 10 | 145600 | N11000111K-140 | Raucoset® OR Infusion Set               |
| 11 | 145618 | N11000111K-141 | Raucoset® Dressing Set No. 8            |
| 12 | 145834 | N11000111K-143 | Raucoset® Probe Set No. 2               |
| 13 | 145892 | N11000111K-147 | Raucoset® Probe Set No. 1 (S)           |
| 14 | 145912 | N11000111K-149 | Raucoset® Tongue Spatula Set            |
| 15 | 145346 | N11000111K-155 | Raucoset® Emesis Basin                  |
| 16 | 145356 | N11000111K-159 | Raucoset® Disinfection Set              |
| 17 | 145365 | N11000111K-160 | Raucoset® Dressing Set No. 1            |
| 18 | 145371 | N11000111K-161 | Raucoset® Dialysis Set                  |
| 19 | 145390 | N11000111K-162 | Raucoset® Narcosis Set                  |
| 20 | 145468 | N11000111K-164 | Raucoset® Dialysis Set                  |
| 21 | 145718 | N11000111K-168 | Raucoset® Catheter Set                  |
| 22 | 145305 | N11000111K-175 | Raucoset® Home Care Set                 |
| 23 | 145055 | N11000111K-176 | Raucoset® Mouth Care Set                |
| 24 | 145722 | N11000111K-127 | Raucoset® Set 3 Gauze Balls NW 64       |
| 25 | 145573 | N11000111K-169 | Raucoset® Dressing Set No. 7            |
| 26 | 145553 | N11000111K-133 | Raucoset® Probe Set                     |
| 27 | 145314 | N11000111K-172 | Raucoset® Nonwoven Injection Set        |
| 28 | 145451 | N11000111K-137 | Raucoset® Probe Set                     |
| 29 | 145458 | N11000111K-139 | Raucoset® Probe Set                     |
| 30 | 145802 | N11000111K-142 | Raucoset® Dressing Set No. 4            |
| 31 | 145833 | N11000111K-170 | Raucoset® Dressing Set No. 1            |
| 32 | 145836 | N11000111K-174 | Raucoset® Dressing Set No. 2            |
| 33 | 145838 | N11000111K-144 | Raucoset® Disinfection Set S.O.P.       |
| 34 | 145841 | N11000111K-165 | Raucoset® Dressing Set No. 3            |
| 35 | 145844 | N11000111K-145 | Raucoset® Disinfection Set, alternative |
| 36 | 145850 | N11000111K-173 | Raucoset® Dressing Set No. 6            |
| 37 | 145876 | N11000111K-146 | Raucoset® Universal Dressing Set        |
| 38 | 145893 | N11000111K-148 | Raucoset® Set anatomical forceps, blue  |
| 39 | 145035 | N11000111K-180 | Raucoset® 5 Gynaecology Dressings       |
| 40 | 145087 | N11000111K-171 | Raucoset® Set 5 Gauze Balls 62          |
| 41 | 145092 | N11000111K-150 | Raucoset® Venous Puncture Set           |
| 42 | 145106 | N11000111K-151 | Raucoset® Disinfection Set              |
| 43 | 145304 | N11000111K-152 | Raucoset® Anaesthesia Set               |
| 44 | 145313 | N11000111K-153 | Raucoset® Disinfection Set              |
| 45 | 145318 | N11000111K-154 | Raucoset® Dressing Set No. 5            |
| 46 | 145319 | N11000111K-167 | Raucoset® Dressing Set                  |
| 47 | 145442 | N11000111K-163 | Raucoset® Probe Set                     |
| 48 | 145034 | N11000111K-181 | Raucoset® 10 Gynaecology Dressings      |

## Manufacturer's Declaration

In relation to Regulation 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*<sup>1</sup>
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

|                                                 |                                                                                                                                                                                                                                                                                                                      |
|-------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Manufacturer name                               | Xuchang Zhende Surgical Dressing Co., Ltd.                                                                                                                                                                                                                                                                           |
| Manufacturer address and contact details        | Site 1: No. 1 Jinhui Road, Industry Cluster District, Yanling County 461200, Xuchang City, Henan Province, PEOPLE'S REPUBLIC OF CHINA<br>Site 2(Legal manufacturer): Area A, Baihua Road East, South Side of Erji river, Industry cluster district, Yanling county 461200 Xuchang, Henan, PEOPLE'S REPUBLIC OF CHINA |
| Single Registration Number (SRN) (if available) | CN-MF-000009222                                                                                                                                                                                                                                                                                                      |

|                                                       |                                                  |
|-------------------------------------------------------|--------------------------------------------------|
| Authorised Representative name (if applicable)        | Shanghai International Holding Corp.GmbH(Europe) |
| Authorised Representative address and contact details | Eiffestraße 80, 20537 Hamburg, Germany.          |
| Single Registration Number (SRN) (if available)       | DE-AR-000000001                                  |

|                                                                                                           |                                                           |
|-----------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|
| Notified body name (if applicable)                                                                        | <input checked="" type="checkbox"/> See attached schedule |
| Notified body number (if applicable)                                                                      | <input checked="" type="checkbox"/> See attached schedule |
| Directive Certificate number(s) to which this confirmation is made (if applicable)                        | <input checked="" type="checkbox"/> See attached schedule |
| Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if | <input checked="" type="checkbox"/> See attached schedule |

<sup>1</sup> The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

|                                                 |                                                           |
|-------------------------------------------------|-----------------------------------------------------------|
| applicable)                                     |                                                           |
| End date of extended validity/transition period | <input checked="" type="checkbox"/> See attached schedule |

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*<sup>2</sup>
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➤ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021, was/were not withdrawn by 20 March 2023
- *Choose applicable statements:*

☐ Expired *before* 20 March 2023:

- ☐ Before the original date of expiry as indicated on the Directive Certificate, we and the notified body have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device
- ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request)
- ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

☒ Expired/expires *after* 20 March 2023:

- ☒ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

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<sup>2</sup> The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

*Choose one applicable statement:*

- ☐ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ **Quality Management System (QMS)**

- *Choose one applicable statement:*

- ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- ☒ A QMS in accordance with Article 10(9) MDR is in place.
- ☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➤ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- The device(s) has/have not been significantly changed in its/their design and intended purpose since 26 May 2021.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

**Signed for and on behalf of the manufacturer:**

### Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| <b>Identification of the device</b><br>(e.g., device name,<br>family/group name<br>device model or<br>catalogue number) | <b>Directive Certificate<br/>number(s)<br/>to which this<br/>confirmation is<br/>made</b><br>(if applicable) | <b>Original expiry date<br/>as indicated on the<br/>Directive Certificate<br/>prior to the<br/>extension of the<br/>validity</b><br>(if applicable) | <b>Notified Body name<br/>and number</b>   | <b>End date of<br/>extended<br/>validity/transition<br/>period</b> | <b>Substitute Device</b><br>(if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|--------------------------------------------------------------------|---------------------------------------------|
| Procedural Dressing<br>Trays                                                                                            | G1 109397 0004<br>Rev. 00                                                                                    | 2024-03-03                                                                                                                                          | TÜV SÜD Product<br>Service GmbH,<br>CE0123 | 2028-12-31                                                         | N/A                                         |