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# Tianjin Huahong Technology Co., Ltd.

## Lancing device

## DECLARATION of CONFORMITY

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| Drafted by: | 米晓熙 2021-05-12 |
| Reviewed by: | 2021-05-12 |
| Approved by: | 2021.05.12 |
| File number: | HH-JS-TF-03-09 |
| Revision | A/4 |
| Effective | 2021-05-12 |

# Documents Revision History

| Version | Revision History | Effective Date | Remarks |
|---|---|---|---|
| A/0 | Original | 2017.10.12 | |
| A/1 | Add new model | 2018.5.10 | |
| A/2 | Add new model | 2019.8.20 | |
| A/3 | Add new model | 2020.11.27 | |
| A/4 | Update according to MDR requirements | 2021.05.12 | |
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# EC DECLARATION OF CONFORMITY

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| Name and address of the manufacturer: / | **Tianjin Huahong Technology Co., Ltd.**<br>**A01, Plant B, No.278, Hangkong Road,Tianjin Pilot Free Trade Zone (Air Port Industrial Park), Tianjin 300308, China** |
| EC Authorized Representative:/ | **Shanghai International Holding Corp. GmbH (Europe)**<br>**Eiffestrasse 80, 20537 Hamburg, Germany** |

**We declare under our sole responsibility that:**

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|---|---|
| Name of the medical device: / | **Lancing device** |
| Product code:/ | **UMDNS code 16380 (Lancing Devices, Blood)** |
| Intended purpose:/ | **Work with the lancet, the lancing device is used to collect capillary blood sample.** |
| Basic UDI-DI:/ | **NA** |
| Trade name:/ | **None** |
| of class: / | **Rule1, Class I**<br>according to annex VIII of Regulation (EU) 2017/745 . |
| CS reference: /<br>Conformity assessment: / | **None**<br>**Declare the conformity of the above mentioned products by issuing this EU Declaration of Conformity after drawing up the technical documentation set out in Annexes II and III of Regulation (EU) 2017/745 .**<br>according to Article 52(7) of Regulation (EU) 2017/745 / |

Meets the provisions of the Regulation EU 2017/745(MDR) which apply to it. The declaration is valid in connection with the "final inspection report" of the device. /

Tianjin 2021.05.12

Ort, Datum / Place, date /
Lieu, date / Luogo, data

GM

Name und Funktion / Name and function /
Nom et fonction / Nome e funzione