



GIOTECH
吉澳科技

Room D-209, No.85 Luojia Cun Shilian Road,
Dalong Street Panyu District Guangzhou,
511430 China

EU Declaration of Conformity

GUANGZHOU GIOTECH CO., LTD

We hereby declare under our sole responsibility that the aforementioned products comply with the requirements of the Regulation on Medical Devices **(EU) 2017/745** of April 5. This declaration is supported by the approval of the ISO 13485:2016 Quality System issued by NQA (Reg. No. 131072). For the following products:

Product Name:

SUPER ABSORBENT UNDERPAD

UDI Basic: 06976071455381

Product Reference(s):

- Disposable Super Absorbent Underpad 40x60 Reference IC-40X60-40
- Disposable Super Absorbent Underpad 60x60 Reference IC-60X60-40
- Disposable Super Absorbent Underpad 60x90 Reference IC-60X90-70
- Disposable Super Absorbent Underpad 90x150 Reference IC-90X150-70

GMDN Code: 61850

Intended Purpose: Hypoallergenic absorbent protection for single-use with high absorption and retention capacity, designed to absorb and protect the surface from moisture.

Risk Classification: **Class I**, according to Rule 1 and 5 of Annex VIII of the Regulation on Medical Devices **EU 2017/745** of April 5, 2017.

Conformity Assessment Procedure: Annex II and III of the Regulation on Medical Devices **(EU) 2017/745** of April 5, 2017.

The responsible party for this declaration is:

Manufacturer:

GUANGZHOU GIOTECH CO., LTD.

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(X) **Authorized Legal Representative in the European Union:**

ICEMEDICS, S. L.

Calle Eduardo Torroja, 38
28946 Fuenlabrada (Madrid)
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SRN: ES-AR-000035147

This Declaration of Conformity is issued under the responsibility of:

GUANGZHOU GIOTECH CO., LTD.

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Name and Surname:

Position: **General Manager**

Date: **Jan 16, 2023**



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