HUMISS

Declaration of Conformity

Manufacturer: Sichuan Shuer Medical Devices Co, Ltd.
Address: No. 2, Building 37, Haowang Electromechanical & New Materials Industrial Park, No. 24 Jinle Road, Chengdu-Aba Industrial Concentration Development Zone, Jintang County, Chengdu City, Sichuan Province, 610404, P. R. China
SRN: Not assigned yet

Device name:	Medical mask
Model(s):	N95 mask, KN95 mask, flat mask, 3D mask, FFP2 cup shape mask, surgical mask, protective mask
Basic UDI-DI:	697408062SCP001H3
Type:	Class I, rule 1, Annex VIII, chapter III

Conformity Assessment Route: Annex II and Annex III

The manufacturer declares that the device complies with the Medical Device Regulation (EU) 2017/745, Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 20417:2021, ISO 15223-1:2021/Amd.1:2025, EN 62366-1:2015, EN ISO 10993-1:2020, ISO 10993-5:2009, ISO 10993-10:2021, ISO 10993-23:2021, EN 14683:2025

The referred report(s) show that the device complies with standard(s) recognized as giving presumption of compliance with the essential requirements in the specified EU Directive(s). The manufacturer has marked the device with the CE mark.

European Authorized Representative
HUMISS TRADING S. L.
Address: Calle Luis Buñuel 12, MADRID, 28018, Spain
Tel: +34-640150649
E-mail: info@humiss.com
SRN: ES-AR-000040177

CE

This declaration is issued under the sole responsibility of the manufacturer.

Haisheng Yue
Signature of Authorized Person
Haisheng Yue
Title: Technical director
Place: Chengdu City

DOC №: S-YQ-MD-2601070098/01
Issue date: Jan. 07, 2026

HUMISS

Declaration of Conformity

Manufacturer: Sichuan Shuer Medical Devices Co, Ltd.
Address: No. 2, Building 37, Haowang Electromechanical & New Materials Industrial Park, No. 24 Jinle Road, Chengdu-Aba Industrial Concentration Development Zone, Jintang County, Chengdu City, Sichuan Province, 610404, P. R. China
SRN: Not assigned yet

Device name:	Medical absorbent pad
Model(s):	Fluid Absorption Pad, Unfluid absorption pad
Basic UDI-DI:	697408062SCP007HF
Type:	Class I, rule 1, Annex VIII, chapter III
Conformity Assessment Route:	Annex II and Annex III

The manufacturer declares that the device complies with the Medical Device Regulation (EU) 2017/745, Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 20417:2021, ISO 15223-1:2021/Amd.1:2025, EN 62366-1:2015, EN ISO 10993-1:2020, ISO 10993-5:2009, ISO 10993-10:2021, ISO 10993-23:2021

The referred report(s) show that the device complies with standard(s) recognized as giving presumption of compliance with the essential requirements in the specified EU Directive(s). The manufacturer has marked the device with the CE mark.

European Authorized Representative
HUMISS TRADING S. L.
Address: Calle Luis Buñuel 12, MADRID, 28018, Spain
Tel: +34-640150649
E-mail: info@humiss.com
SRN: ES-AR-000040177

CE

This declaration is issued under the sole responsibility of the manufacturer.

Haisheng Yue
Signature of Authorized Person
Haisheng Yue
Title: Technical director
Place: Chengdu City

DOC Nº: S-YQ-MD-2601070098/02
Issue date: Jan. 07, 2026

HUMISS

Declaration of Conformity

Manufacturer: Sichuan Shuer Medical Devices Co, Ltd.
Address: No. 2, Building 37, Haowang Electromechanical & New Materials Industrial Park, No. 24 Jinle Road, Chengdu-Aba Industrial Concentration Development Zone, Jintang County, Chengdu City, Sichuan Province, 610404, P. R. China
SRN: Not assigned yet

Device name: Medical wipes
Model(s): N/A
Basic UDI-DI: 697408062SCP113HF
Type: Class I, rule 1, Annex VIII, chapter III

Conformity Assessment Route: Annex II and Annex III

The manufacturer declares that the device complies with the Medical Device Regulation (EU) 2017/745, Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 20417:2021, ISO 15223-1:2021/Amd.1:2025, EN 62366-1:2015, EN ISO 10993-1:2020, ISO 10993-5:2009, ISO 10993-10:2021, ISO 10993-23:2021

The referred report(s) show that the device complies with standard(s) recognized as giving presumption of compliance with the essential requirements in the specified EU Directive(s). The manufacturer has marked the device with the CE mark.

European Authorized Representative
HUMISS TRADING S. L.
Address: Calle Luis Buñuel 12, MADRID, 28018, Spain
Tel: +34-640150649
E-mail: info@humiss.com
SRN: ES-AR-000040177

CE

This declaration is issued under the sole responsibility of the manufacturer.

Haisheng Yue

Signature of Authorized Person
Haisheng Yue
Title: Technical director
Place: Chengdu City

DOC №: S-YQ-MD-2601070098/03
Issue date: Jan. 07, 2026

HUMISS

Declaration of Conformity

Manufacturer: Sichuan Shuer Medical Devices Co, Ltd.
Address: No. 2, Building 37, Haowang Electromechanical & New Materials Industrial Park, No. 24 Jinle Road, Chengdu-Aba Industrial Concentration Development Zone, Jintang County, Chengdu City, Sichuan Province, 610404, P. R. China
SRN: Not assigned yet

Device name: Medical care pad
Model(s): S, M, L, XL, XXL, XXXL
Basic UDI-DI: 697408062SCP011H6
Type: Class I, rule 1, Annex VIII, chapter III

Conformity Assessment Route: Annex II and Annex III

The manufacturer declares that the device complies with the Medical Device Regulation (EU) 2017/745, Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 20417:2021, ISO 15223-1:2021/Amd.1:2025, EN 62366-1:2015, EN ISO 10993-1:2020, ISO 10993-5:2009, ISO 10993-10:2021, ISO 10993-23:2021

The referred report(s) show that the device complies with standard(s) recognized as giving presumption of compliance with the essential requirements in the specified EU Directive(s). The manufacturer has marked the device with the CE mark.

European Authorized Representative
HUMISS TRADING S. L.
Address: Calle Luis Buñuel 12, MADRID, 28018, Spain
Tel: +34-640150649
E-mail: info@humiss.com
SRN: ES-AR-000040177

CE

This declaration is issued under the sole responsibility of the manufacturer.

Haisheng Yue

Signature of Authorized Person
Haisheng Yue
Title: Technical director
Place: Chengdu City

DOC №: S-YQ-MD-2601070098/04
Issue date: Jan. 07, 2026

HUMISS

Declaration of Conformity

Manufacturer: Sichuan Shuer Medical Devices Co, Ltd.
Address: No. 2, Building 37, Haowang Electromechanical & New Materials Industrial Park, No. 24 Jinle Road, Chengdu-Aba Industrial Concentration Development Zone, Jintang County, Chengdu City, Sichuan Province, 610404, P. R. China
SRN: Not assigned yet

Device name: Medical PLA Isolation gown
Model(s): S, M, L, XL, XXL, XXXL
Basic UDI-DI: 697408062SCP053HN
Type: Class I, rule 1, Annex VIII, chapter III

Conformity Assessment Route: Annex II and Annex III

The manufacturer declares that the device complies with the Medical Device Regulation (EU) 2017/745, Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 20417:2021, ISO 15223-1:2021/Amd.1:2025, EN 62366-1:2015, EN ISO 10993-1:2020, ISO 10993-5:2009, ISO 10993-10:2021, ISO 10993-23:2021

The referred report(s) show that the device complies with standard(s) recognized as giving presumption of compliance with the essential requirements in the specified EU Directive(s). The manufacturer has marked the device with the CE mark.

European Authorized Representative
HUMISS TRADING S. L.
Address: Calle Luis Buñuel 12, MADRID, 28018, Spain
Tel: +34-640150649
E-mail: info@humiss.com
SRN: ES-AR-000040177

CE

This declaration is issued under the sole responsibility of the manufacturer.

Haisheng Yue
Signature of Authorized Person
Haisheng Yue
Title: Technical director
Place: Chengdu City

DOC №: S-YQ-MD-2601070098/05
Issue date: Jan. 07, 2026

HUMISS

Declaration of Conformity

Manufacturer: Sichuan Shuer Medical Devices Co, Ltd.
Address: No. 2, Building 37, Haowang Electromechanical & New Materials Industrial Park, No. 24 Jinle Road, Chengdu-Aba Industrial Concentration Development Zone, Jintang County, Chengdu City, Sichuan Province, 610404, P. R. China
SRN: Not assigned yet

Device name: Medical PLA protective suit
Model(s): S, M, L, XL, XXL, XXXL
Basic UDI-DI: 697408062SCP054HQ
Type: Class I, rule 1, Annex VIII, chapter III

Conformity Assessment Route: Annex II and Annex III

The manufacturer declares that the device complies with the Medical Device Regulation (EU) 2017/745, Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 20417:2021, ISO 15223-1:2021/Amd.1:2025, EN 62366-1:2015, EN ISO 10993-1:2020, ISO 10993-5:2009, ISO 10993-10:2021, ISO 10993-23:2021

The referred report(s) show that the device complies with standard(s) recognized as giving presumption of compliance with the essential requirements in the specified EU Directive(s). The manufacturer has marked the device with the CE mark.

European Authorized Representative
HUMISS TRADING S. L.
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E-mail: info@humiss.com
SRN: ES-AR-000040177

CE

This declaration is issued under the sole responsibility of the manufacturer.

Haisheng Yue

Signature of Authorized Person
Haisheng Yue
Title: Technical director
Place: Chengdu City

DOC №: S-YQ-MD-2601070098/06
Issue date: Jan. 07, 2026

HUMISS

Declaration of Conformity

Manufacturer: Sichuan Shuer Medical Devices Co, Ltd.
Address: No. 2, Building 37, Haowang Electromechanical & New Materials Industrial Park, No. 24 Jinle Road, Chengdu-Aba Industrial Concentration Development Zone, Jintang County, Chengdu City, Sichuan Province, 610404, P. R. China
SRN: Not assigned yet

Device name: Medical PLA underpad
Model(s): S, M, L, XL, XXL, XXXL
Basic UDI-DI: 697408062SCP057HW
Type: Class I, rule 1, Annex VIII, chapter III

Conformity Assessment Route: Annex II and Annex III

The manufacturer declares that the device complies with the Medical Device Regulation (EU) 2017/745, Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 20417:2021, ISO 15223-1:2021/Amd.1:2025, EN 62366-1:2015, EN ISO 10993-1:2020, ISO 10993-5:2009, ISO 10993-10:2021, ISO 10993-23:2021

The referred report(s) show that the device complies with standard(s) recognized as giving presumption of compliance with the essential requirements in the specified EU Directive(s). The manufacturer has marked the device with the CE mark.

European Authorized Representative
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E-mail: info@humiss.com
SRN: ES-AR-000040177

CE

This declaration is issued under the sole responsibility of the manufacturer.

Haisheng Yue
Signature of Authorized Person
Haisheng Yue
Title: Technical director
Place: Chengdu City

DOC №: S-YQ-MD-2601070098/07
Issue date: Jan. 07, 2026

HUMISS

Declaration of Conformity

Manufacturer: Sichuan Shuer Medical Devices Co, Ltd.
Address: No. 2, Building 37, Haowang Electromechanical & New Materials Industrial Park, No. 24 Jinle Road, Chengdu-Aba Industrial Concentration Development Zone, Jintang County, Chengdu City, Sichuan Province, 610404, P. R. China
SRN: Not assigned yet

Device name: PLA care pad
Model(s): S, M, L, XL, XXL, XXXL
Basic UDI-DI: 697408062SCP059J2
Type: Class I, rule 1, Annex VIII, chapter III

Conformity Assessment Route: Annex II and Annex III

The manufacturer declares that the device complies with the Medical Device Regulation (EU) 2017/745, Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 20417:2021, ISO 15223-1:2021/Amd.1:2025, EN 62366-1:2015, EN ISO 10993-1:2020, ISO 10993-5:2009, ISO 10993-10:2021, ISO 10993-23:2021

The referred report(s) show that the device complies with standard(s) recognized as giving presumption of compliance with the essential requirements in the specified EU Directive(s). The manufacturer has marked the device with the CE mark.

European Authorized Representative
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E-mail: info@humiss.com
SRN: ES-AR-000040177

CE

This declaration is issued under the sole responsibility of the manufacturer.

Haisheng Yue

Signature of Authorized Person
Haisheng Yue
Title: Technical director
Place: Chengdu City

DOC №: S-YQ-MD-2601070098/08
Issue date: Jan. 07, 2026

HUMISS

Declaration of Conformity

Manufacturer: Sichuan Shuer Medical Devices Co, Ltd.
Address: No. 2, Building 37, Haowang Electromechanical & New Materials Industrial Park, No. 24 Jinle Road, Chengdu-Aba Industrial Concentration Development Zone, Jintang County, Chengdu City, Sichuan Province, 610404, P. R. China
SRN: Not assigned yet

Device name: PLA shoecover
Model(s): S, M, L, XL
Basic UDI-DI: 697408062SCP055HS
Type: Class I, rule 1, Annex VIII, chapter III

Conformity Assessment Route: Annex II and Annex III

The manufacturer declares that the device complies with the Medical Device Regulation (EU) 2017/745, Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 20417:2021, ISO 15223-1:2021/Amd.1:2025, EN 62366-1:2015, EN ISO 10993-1:2020, ISO 10993-5:2009, ISO 10993-10:2021, ISO 10993-23:2021

The referred report(s) show that the device complies with standard(s) recognized as giving presumption of compliance with the essential requirements in the specified EU Directive(s). The manufacturer has marked the device with the CE mark.

European Authorized Representative
HUMISS TRADING S. L.
Address: Calle Luis Buñuel 12, MADRID, 28018, Spain
Tel: +34-640150649
E-mail: info@humiss.com
SRN: ES-AR-000040177

CE

This declaration is issued under the sole responsibility of the manufacturer.

Haisheng Yue
Signature of Authorized Person
Haisheng Yue
Title: Technical director
Place: Chengdu City

DOC №: S-YQ-MD-2601070098/09
Issue date: Jan. 07, 2026

HUMISS

Declaration of Conformity

Manufacturer: Sichuan Shuer Medical Devices Co, Ltd.
Address: No. 2, Building 37, Haowang Electromechanical & New Materials Industrial Park, No. 24 Jinle Road, Chengdu-Aba Industrial Concentration Development Zone, Jintang County, Chengdu City, Sichuan Province, 610404, P. R. China
SRN: Not assigned yet

Device name: PLA protective cap
Model(s): S, M, L, XL
Basic UDI-DI: 697408062SCP056HU
Type: Class I, rule 1, Annex VIII, chapter III

Conformity Assessment Route: Annex II and Annex III

The manufacturer declares that the device complies with the Medical Device Regulation (EU) 2017/745, Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 20417:2021, ISO 15223-1:2021/Amd.1:2025, EN 62366-1:2015, EN ISO 10993-1:2020, ISO 10993-5:2009, ISO 10993-10:2021, ISO 10993-23:2021

The referred report(s) show that the device complies with standard(s) recognized as giving presumption of compliance with the essential requirements in the specified EU Directive(s). The manufacturer has marked the device with the CE mark.

European Authorized Representative
HUMISS TRADING S. L.
Address: Calle Luis Buñuel 12, MADRID, 28018, Spain
Tel: +34-640150649
E-mail: info@humiss.com
SRN: ES-AR-000040177

CE

This declaration is issued under the sole responsibility of the manufacturer.

Signature of Authorized Person
Haisheng Yue
Title: Technical director
Place: Chengdu City

DOC №: S-YQ-MD-2601070098/10
Issue date: Jan. 07, 2026

HUMISS

Declaration of Conformity

Manufacturer: Sichuan Shuer Medical Devices Co, Ltd.
Address: No. 2, Building 37, Haowang Electromechanical & New Materials Industrial Park, No. 24 Jinle Road, Chengdu-Aba Industrial Concentration Development Zone, Jintang County, Chengdu City, Sichuan Province, 610404, P. R. China
SRN: Not assigned yet

Device name: Medical Graphene Isolation gown
Model(s): S, M, L, XL, XXL, XXXL
Basic UDI-DI: 697408062SCP068J3
Type: Class I, rule 1, Annex VIII, chapter III

Conformity Assessment Route: Annex II and Annex III

The manufacturer declares that the device complies with the Medical Device Regulation (EU) 2017/745, Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 20417:2021, ISO 15223-1:2021/Amd.1:2025, EN 62366-1:2015, EN ISO 10993-1:2020, ISO 10993-5:2009, ISO 10993-10:2021, ISO 10993-23:2021

The referred report(s) show that the device complies with standard(s) recognized as giving presumption of compliance with the essential requirements in the specified EU Directive(s). The manufacturer has marked the device with the CE mark.

European Authorized Representative
HUMISS TRADING S. L.
Address: Calle Luis Buñuel 12, MADRID, 28018, Spain
Tel: +34-640150649
E-mail: info@humiss.com
SRN: ES-AR-000040177

CE

This declaration is issued under the sole responsibility of the manufacturer.

Signature of Authorized Person
Haisheng Yue
Title: Technical director
Place: Chengdu City

DOC Nº: S-YQ-MD-2601070098/11
Issue date: Jan. 07, 2026

HUMISS

Declaration of Conformity

Manufacturer: Sichuan Shuer Medical Devices Co, Ltd.
Address: No. 2, Building 37, Haowang Electromechanical & New Materials Industrial Park, No. 24 Jinle Road, Chengdu-Aba Industrial Concentration Development Zone, Jintang County, Chengdu City, Sichuan Province, 610404, P. R. China
SRN: Not assigned yet

Device name:	Medical Graphene protective suit
Model(s):	S, M, L, XL, XXL, XXXL
Basic UDI-DI:	697408062SCP031HC
Type:	Class I, rule 1, Annex VIII, chapter III
Conformity Assessment Route:	Annex II and Annex III

The manufacturer declares that the device complies with the Medical Device Regulation (EU) 2017/745, Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 20417:2021, ISO 15223-1:2021/Amd.1:2025, EN 62366-1:2015, EN ISO 10993-1:2020, ISO 10993-5:2009, ISO 10993-10:2021, ISO 10993-23:2021

The referred report(s) show that the device complies with standard(s) recognized as giving presumption of compliance with the essential requirements in the specified EU Directive(s). The manufacturer has marked the device with the CE mark.

European Authorized Representative
HUMISS TRADING S. L.
Address: Calle Luis Buñuel 12, MADRID, 28018, Spain
Tel: +34-640150649
E-mail: info@humiss.com
SRN: ES-AR-000040177

CE

This declaration is issued under the sole responsibility of the manufacturer.

Signature of Authorized Person
Haisheng Yue
Title: Technical director
Place: Chengdu City

DOC Nº: S-YQ-MD-2601070098/12
Issue date: Jan. 07, 2026

HUMISS

Declaration of Conformity

Manufacturer: Sichuan Shuer Medical Devices Co, Ltd.
Address: No. 2, Building 37, Haowang Electromechanical & New Materials Industrial Park, No. 24 Jinle Road, Chengdu-Aba Industrial Concentration Development Zone, Jintang County, Chengdu City, Sichuan Province, 610404, P. R. China
SRN: Not assigned yet

Device name: Medical Graphene under pad
Model(s): S, M, L, XL, XXL, XXXL
Basic UDI-DI: 697408062SCP008HH
Type: Class I, rule 1, Annex VIII, chapter III

Conformity Assessment Route: Annex II and Annex III

The manufacturer declares that the device complies with the Medical Device Regulation (EU) 2017/745, Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 20417:2021, ISO 15223-1:2021/Amd.1:2025, EN 62366-1:2015, EN ISO 10993-1:2020, ISO 10993-5:2009, ISO 10993-10:2021, ISO 10993-23:2021

The referred report(s) show that the device complies with standard(s) recognized as giving presumption of compliance with the essential requirements in the specified EU Directive(s). The manufacturer has marked the device with the CE mark.

European Authorized Representative
HUMISS TRADING S. L.
Address: Calle Luis Buñuel 12, MADRID, 28018, Spain
Tel: +34-640150649
E-mail: info@humiss.com
SRN: ES-AR-000040177

CE

This declaration is issued under the sole responsibility of the manufacturer.

Signature of Authorized Person
Haisheng Yue
Title: Technical director
Place: Chengdu City

DOC №: S-YQ-MD-2601070098/13
Issue date: Jan. 07, 2026

HUMISS

Declaration of Conformity

Manufacturer: Sichuan Shuer Medical Devices Co, Ltd.
Address: No. 2, Building 37, Haowang Electromechanical & New Materials Industrial Park, No. 24 Jinle Road, Chengdu-Aba Industrial Concentration Development Zone, Jintang County, Chengdu City, Sichuan Province, 610404, P. R. China
SRN: Not assigned yet

Device name: Graphene shoe cover
Model(s): S, M, L, XL
Basic UDI-DI: 697408062SCP025HH
Type: Class I, rule 1, Annex VIII, chapter III

Conformity Assessment Route: Annex II and Annex III

The manufacturer declares that the device complies with the Medical Device Regulation (EU) 2017/745, Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 20417:2021, ISO 15223-1:2021/Amd.1:2025, EN 62366-1:2015, EN ISO 10993-1:2020, ISO 10993-5:2009, ISO 10993-10:2021, ISO 10993-23:2021

The referred report(s) show that the device complies with standard(s) recognized as giving presumption of compliance with the essential requirements in the specified EU Directive(s). The manufacturer has marked the device with the CE mark.

European Authorized Representative
HUMISS TRADING S. L.
Address: Calle Luis Buñuel 12, MADRID, 28018, Spain
Tel: +34-640150649
E-mail: info@humiss.com
SRN: ES-AR-000040177

CE

This declaration is issued under the sole responsibility of the manufacturer.

Signature of Authorized Person
Haisheng Yue
Title: Technical director
Place: Chengdu City

DOC Nº: S-YQ-MD-2601070098/14
Issue date: Jan. 07, 2026

HUMISS

Declaration of Conformity

Manufacturer: Sichuan Shuer Medical Devices Co, Ltd.
Address: No. 2, Building 37, Haowang Electromechanical & New Materials Industrial Park, No. 24 Jinle Road, Chengdu-Aba Industrial Concentration Development Zone, Jintang County, Chengdu City, Sichuan Province, 610404, P. R. China
SRN: Not assigned yet

Device name: Graphene protective cap
Model(s): S, M, L, XL
Basic UDI-DI: 697408062SCP026HK
Type: Class I, rule 1, Annex VIII, chapter III

Conformity Assessment Route: Annex II and Annex III

The manufacturer declares that the device complies with the Medical Device Regulation (EU) 2017/745, Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 20417:2021, ISO 15223-1:2021/Amd.1:2025, EN 62366-1:2015, EN ISO 10993-1:2020, ISO 10993-5:2009, ISO 10993-10:2021, ISO 10993-23:2021

The referred report(s) show that the device complies with standard(s) recognized as giving presumption of compliance with the essential requirements in the specified EU Directive(s). The manufacturer has marked the device with the CE mark.

European Authorized Representative
HUMISS TRADING S. L.
Address: Calle Luis Buñuel 12, MADRID, 28018, Spain
Tel: +34-640150649
E-mail: info@humiss.com
SRN: ES-AR-000040177

CE

This declaration is issued under the sole responsibility of the manufacturer.

Haisheng Yue
Signature of Authorized Person
Haisheng Yue
Title: Technical director
Place: Chengdu City

DOC №: S-YQ-MD-2601070098/15
Issue date: Jan. 07, 2026

HUMISS

Declaration of Conformity

Manufacturer: Sichuan Shuer Medical Devices Co, Ltd.
Address: No. 2, Building 37, Haowang Electromechanical & New Materials Industrial Park, No. 24 Jinle Road, Chengdu-Aba Industrial Concentration Development Zone, Jintang County, Chengdu City, Sichuan Province, 610404, P. R. China
SRN: Not assigned yet

Device name: Graphene diaper
Model(s): S, M, L, XL, XXL, XXXL
Basic UDI-DI: 697408062SCP018HL
Type: Class I, rule 1, Annex VIII, chapter III

Conformity Assessment Route: Annex II and Annex III

The manufacturer declares that the device complies with the Medical Device Regulation (EU) 2017/745, Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 20417:2021, ISO 15223-1:2021/Amd.1:2025, EN 62366-1:2015, EN ISO 10993-1:2020, ISO 10993-5:2009, ISO 10993-10:2021, ISO 10993-23:2021

The referred report(s) show that the device complies with standard(s) recognized as giving presumption of compliance with the essential requirements in the specified EU Directive(s). The manufacturer has marked the device with the CE mark.

European Authorized Representative
HUMISS TRADING S. L.
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Tel: +34-640150649
E-mail: info@humiss.com
SRN: ES-AR-000040177

CE

This declaration is issued under the sole responsibility of the manufacturer.

Signature of Authorized Person
Haisheng Yue
Title: Technical director
Place: Chengdu City

DOC Nº: S-YQ-MD-2601070098/16
Issue date: Jan. 07, 2026

HUMISS

Declaration of Conformity

Manufacturer: Sichuan Shuer Medical Devices Co, Ltd.
Address: No. 2, Building 37, Haowang Electromechanical & New Materials Industrial Park, No. 24 Jinle Road, Chengdu-Aba Industrial Concentration Development Zone, Jintang County, Chengdu City, Sichuan Province, 610404, P. R. China
SRN: Not assigned yet

Device name: Graphene care pad
Model(s): S, M, L, XL, XXL, XXXL
Basic UDI-DI: 697408062SCP020H7
Type: Class I, rule 1, Annex VIII, chapter III
Conformity Assessment Route: Annex II and Annex III

The manufacturer declares that the device complies with the Medical Device Regulation (EU) 2017/745, Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 20417:2021, ISO 15223-1:2021/Amd.1:2025, EN 62366-1:2015, EN ISO 10993-1:2020, ISO 10993-5:2009, ISO 10993-10:2021, ISO 10993-23:2021

The referred report(s) show that the device complies with standard(s) recognized as giving presumption of compliance with the essential requirements in the specified EU Directive(s). The manufacturer has marked the device with the CE mark.

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CE

This declaration is issued under the sole responsibility of the manufacturer.

Signature of Authorized Person
Haisheng Yue
Title: Technical director
Place: Chengdu City

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