

# EU CERTIFICATE OF CONFORMITY

Ref. No.: HT2403105M01

**Applicant :** Dongguan S-King Insoles Limited  
Room 101, Building 2, No.10, Yizhan Road, Nancheng Street,  
Dongguan City, Guangdong Province, China

**Manufacturer :** Dongguan S-King Insoles Limited  
Room 101, Building 2, No.10, Yizhan Road,  
Nancheng Street, Dongguan City,  
Guangdong Province, China

**Product :** See Annex

**Trademark :** /

| CONFORMITY DETAILS     |                            |                 |
|------------------------|----------------------------|-----------------|
| REGULATION             | APPLICABLE STANDARD(S)     | TEST REPORT NO. |
| (EU) 2017/745<br>(MDR) | EN ISO 15223-1:2021        | TR2403105M01    |
|                        | EN ISO 20417:2021          |                 |
|                        | EN ISO 14971:2019+A11:2021 |                 |
|                        | EN ISO 10993-1:2020        |                 |
|                        | EN ISO 10993-5:2009        |                 |
|                        | EN ISO 10993-10:2023       |                 |

We confirm that the Technical Documentation for the above-mentioned Product complies with the applicable requirements of the Regulation (EU) 2017/745.

Referring to the intended use, we have conducted with successful results the review of the Manufacturer's Technical Documentation of the certified product according to the above-mentioned Directive and the applicable standards.

This Certificate is issued under the following conditions:

- 1) The Manufacturer's Technical Documentation, as required for Class I Devices (non-sterile, without measuring function, non-reusable surgical instrument), has been reviewed according to Annexes II and III (Article 52, point 7).
- 2) It applies only to the above-mentioned Medical Devices.
- 3) The Manufacturer is obligated to assure conformity of all the Medical Devices of the respective model to the type assessed by the mean of this Certificate.
- 4) Any significant changes in the Design or Process used to manufacture the Product, or revision to the Directives or standards referred above may require a special audit by us.



After fulfilling the relevant EU Legislation Requirements, the Manufacturer shall affix to each Medical Device, CE Marking according to the above example. This certificate expires upon the withdrawal of one of the above-mentioned standards.

# ANNEX TO CERTIFICATE

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| Products         | Model / Type No.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| PU Insoles       | PX101-PX1999, PH101-PH1999, PL101-PL1999, PW101-PW1999<br>PX201-PX2999, PH201-PH2999, PL201-PL2999, PW201-PW2999<br>PX301-PX3999, PH301-PH3999, PL301-PL3999, PW301-PW3999<br>PX401-PX4999, PH401-PH4999, PL401-PL4999, PW401-PW4999<br>PX501-PX5999, PH501-PH5999, PL501-PL5999, PW501-PW5999<br>PH601-PH6999, PL601-PL6999, PW601-PW6999 PS101-PS1999,<br>PF101-PF1999, SK10001-SK19999<br>PZ101-PZ1999, PZ201-PZ2999, PS201-PS2999, PF201-PF2999<br>PZ301-PZ3999, PS301-PS3999, PF301-PF3999, PZ401-PZ4999<br>PS401-PS4999, PF401-PF4999, PZ501-PZ5999, PS501-PS5999<br>PF501-PF5999, PZ601-PZ6999, PS601-PS6999, PF601-PF6999 |
| Gel Insoles      | TY101-TY1999, TP101-TP1999, TS101-TS1999, TZ101-TZ1999<br>TY201-TY2999, TP201-TP2999, TS201-TS2999, TZ201-TZ2999<br>TY301-TY3999, TP301-TP3999, TS301-TS3999, TZ301-TZ3999<br>TY401-TY4999, TP401-TP4999, TS401-TS4999, TZ401-TZ4999<br>TZS101-TZ1999, TP532-1, TP515-1, SK210001-SK29999                                                                                                                                                                                                                                                                                                                                         |
| PU foam insoles  | PD101-PD1999, PC101-PC1999, PP101-PP1999, PJ101-PJ1999<br>PD201-PD2999, PC201-PC2999, PP201-PP2999, PJ201-PJ2999<br>PD301-PD3999, PC301-PC3999, PP301-PP3999, PJ301-PJ3999<br>PD401-PD4999, PC401-PC4999, PP401-PP4999, PJ401-PJ4999<br>PD501-PD5999, PC501-PC5999, PP501-PP5999, PJ501-PJ5999<br>PD601-PD6999, PC601-PC6999, PP601-PP6999, PJ601-PJ6999<br>PJ105-1, PW107, PF1107, PS220, PWL202, SK30001-SK39999                                                                                                                                                                                                                |
| SILICONE INSOLES | SJ101-SJ1999, SJ201-SJ2999, SJ301-SJ3999<br>SJ401-SJ4999, SJ501-SJ5999, SJ601-SJ6999<br>SK40001-SK49999                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| LIQUID INSOLES   | LJ101-LJ199, LM101-LM199, SK50001-SK59999                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |

This Annex is part of a full certificate and should be read in conjunction with it.