

EC DECLARATION OF CONFORMITY

MANUFACTURER

Shenzhen BSX Technology Electronics Co.,Ltd

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Area, No.78 AiNan Road,
Longgang, Shenzhen 518116, Guangdong, China

Whose single Authorized EU-Representative

Luxus Lebenswelt GmbH
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We, the manufacturer, herewith declare that the product:

Infrared Thermometer Model BSX976

meet the provision of Directive 93/42/EEC on Medical Devices (MDD) which apply to them.

The medical device has been assigned to Class IIa according to Annex IX of Directive 93/42/EEC on Medical devices. It bears the mark compliance



on the designated product following with the Directive 93/42/EEC requirements of manufacture concerned with securing and maintaining suitable conditions has been assured by Notified Body (No 0197) through the assessment to the quality management system according to the requirements of Annex II, excluding Section 4 of the Directive 93/42/EEC.

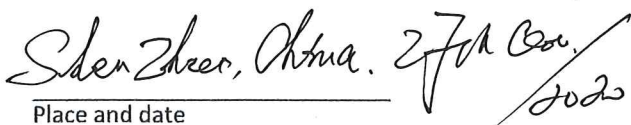
Notified Body: TÜV Rheinland LGA Products GmbH, N° 0197
Certificate No: HD60144431 0001 | Issue date: 2020-03-12 | Expiry date: 2023-12-09

This declaration of conformity covers the medical device as specified above and imported by Paul Stricker SA, under ref.97121, as described in the Instructions Manual (Appendix A) by MANUFACTURER and marked as well as accordingly to Appendix B.

Access to technical information

The MANUFACTURER shall, further to a reasoned request from a competent national authority of any EU member state, provide the DISTRIBUTOR with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the Medical Devices with the Directive 93/42/EEC, in a language which can be easily understood by that authority. They shall cooperate with that authority and the MANUFACTURER, at its request, on any action taken to eliminate the risks posed by medical devices which they have placed on the market.

The above-mentioned declaration of conformity is exclusively under the responsibility of Manufacturer, **Shenzhen BSX Technology Electronics Co., Ltd.**


Place and date



Legally signature/Function
(Official Stamp)