Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 051867 0017 Rev. 00

Manufacturer: **Lucky Healthcare Co., Ltd.**
No.6 Lekai South Street
071054 Baoding, Hebei
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Lucky Healthcare Co., Ltd.
No.6 Lekai South Street, 071054 Baoding, Hebei, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Medical X-ray Film

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: SH19297EXT01

Valid from: 2019-10-14
Valid until: 2024-05-26

Date, 2019-10-14

Stefan Preiß
Head of Certification/Notified Body

Digitally signed by Palii Nina
Date: 2024.01.30 12:50:54 EET
Reason: MoldSign Signature
Location: Moldova

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

A4 / 07.17