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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

G2 001395 0011 Rev. 00

Manufacturer: **OSANG Healthcare Co., Ltd.**
132, Anyangcheondong-ro, Dongan-gu
Anyang-si, Gyeonggi-do 14040
REPUBLIC OF KOREA

EC-Representative: OBELIS S.A
Bd. General Wahis 53, 1030 Brussels, BELGIUM

Product Category(ies): **Sterile Lancets**

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

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Stefan Preiß

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 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT

