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Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
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ZLG-BS-244.10.08



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)

**No. G2 016512 0045 Rev. 00**

**Manufacturer:** **NIHON SEIMITSU SOKKI CO., LTD.**  
2508-13 Nakago, Shibukawa  
Gunma  
377-0293 JAPAN

**EC-Representative:** **Medical Device Safety Service GmbH**  
Schiffgraben 41, 30175 Hannover,  
GERMANY

**Product Category(ies):** **Non-invasive Digital Blood Pressure Monitors,  
Oximeters Pulse, Non-contact Thermometer,  
Capnograph / Pulse Oximeter**

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.

**Report No.:** **JAQ235036893**

**Valid from:** **2019-01-21**  
**Valid until:** **2023-06-18**

**Date,** **2019-01-21**

Stefan Preiß

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 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT

