

EU Certificate

for the assessment of the
quality management system



according to Medical Device Regulation (EU) 2017/745 Annex IX Chapter I+III

As a Notified Body of the European Union DEKRA Certification GmbH certifies, that the
manufacturer

SFM Hospital Products GmbH

Single Registration Number (SRN): DE-MF-000005505

Segelfliegerdamm 67-89, 12487 Berlin, Germany

applies a quality management system according to Annex IX Chapter I+III of the Medical Device Regulation (EU) 2017/745 for the medical devices listed in the annex. This certificate is based on the assessments listed in CNo50759-00 and is only valid in conjunction with the successful completion of the annual surveillance audits.

EU Certificate no.: 50759-60-00-00

Certificate valid from:

2024-08-21

Certificate valid to:

2029-05-02



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

BS-MDR-092

DEKRA Certification GmbH, Stuttgart
Notified Body ID number: 0124

Annex to the EU Certificate no. 50759-60-00-00

Following devices/device categories are included in this certificate:

Class IIa

Name of the device/ device category:

Surgical Gloves, sterile, latex powderfree/powdered; nitrile powderfree,
Basis-UDI-DI 04036534LSGQJ; 04036534NSGQU

Change(s) to previous certificate: n.a.

