



BUREAU
VERITAS

Bureau Veritas Certification

SCANFIL Suzhou Co., Ltd.

No.9 Sheng'ai Lu, LouFeng, Suzhou Industrial Park, JiangSu Province, China

Certified site:

No.9 Sheng'ai Lu, LouFeng, Suzhou Industrial Park, JiangSu Province, China

Bureau Veritas Certification Holding SAS – Italy Branch certifies that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standards detailed below

ISO 13485:2016

Certification scope

Contract manufacturing of active medical devices of patient positioning system and components for active surgical instrument

Original cycle start date:	07/09/2016
Expiry date of previous cycle:	06/09/2025
Certification / Recertification Audit date:	17/04/2025
Certification / Recertification cycle start date:	27/05/2025

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **06/09/2028**

Certificate No. - Version: IT342807-1

Revision date: 27/05/2025


Signed on behalf of BVCH SAS Italy Branch



Membro degli Accordi di Mutuo Riconoscimento EA e IAF
Signatory of EA and IAF Mutual Recognition Agreements

Certification body address: Viale Monza, 347 - 20126 Milano (MI) Italy
Local office: Viale Monza, 347 - 20126 Milano (MI) Italy

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation. To check this certificate validity please refer to the website www.bureauveritas.it

斯凯菲尔电子（苏州）有限公司

苏州工业园区娄葑圣爱路 9 号

认证地址：

苏州工业园区娄葑圣爱路 9 号

必维认证集团认证控股有限公司意大利分公司
确证上述单位的管理体系已经评审
并确认符合下列管理体系标准全部适用条款的要求

ISO 13485:2016

体系覆盖范围

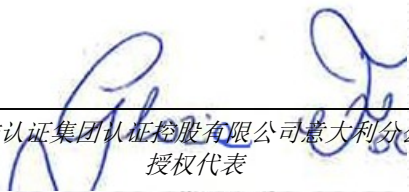
有源手术器械组件和有源医疗器械（患者定位系统）的合约制造

最初认证周期起始日期： 07/09/2016
上一周期的到期日： 06/09/2025
认证/再认证审核日期： 17/04/2025
本次认证/再认证周期起始日期： 27/05/2025

在证书持有者之管理体系持续符合要求的运行条件下，本证书至下述日期有效：
06/09/2028

证书号 - 版本： IT342807 -1

发证日期： 27/05/2025


必维认证集团认证控股有限公司意大利分公司
授权代表



02138

Membro degli Accordi di Mutuo Riconoscimento EA e IAF
Signatory of EA and IAF Mutual Recognition Agreements

认证机构地址： Viale Monza, 347 - 20126 Milano (MI) Italy
当地办公室地址： Viale Monza, 347 - 20126 Milano (MI) Italy

需进一步澄清本证书认证范围及此管理体系要求的适用性，可直接向持证者查询。
要查证本证书之有效状态请查询 www.bureauveritas.it