

彭伟代表国际辐照协会在“中国 X 射线医疗器械灭菌发布会”上的致辞

女士们、先生们，各位同行，大家中午好！

非常荣幸在 Medtec China 2025 这一国际医疗器械设计与制造技术盛会上，与各位相聚；更感荣幸受邀出席由 IBA 携手史帝瑞、辐腾辐照、强生医疗、英国标准协会及杰皓医疗共同举办的“中国 X 射线医疗器械灭菌发布会”。

作为国际辐照协会（iia）中国/亚洲代表，我谨代表协会向本届展会及发布会的隆重召开致以最热烈的祝贺，预祝大会圆满成功！

国际辐照协会是一家非营利国际组织，致力于支持全球辐照产业与科学界安全、有益地利用辐照技术。我们的会员皆为行业翘楚——今天现场即可见到 IBA、史帝瑞、强生医疗等熟悉面孔；在全球医疗领域，雅培、碧迪、拜耳、波士顿科学、思拓凡、ICU 医疗、美敦力、斯卡帕、赛多利斯、施乐辉、威斯派克等亦与 iia 携手同行。

国际辐照协会非常看好和重视中国辐照产业的发展，2023 年邀请我出任中国/亚洲代表，2024 年开通微信公众号和视频号，并在其官网上开通了首个也是迄今唯一一个非英语的中文专区，欢迎大家关注。遗憾的是，迄今尚无中国本土医疗企业加入 iia。我们诚挚期待，在座各位能成为“第一个吃螃蟹的人”，与全球领跑者并肩，共同推动中国辐照技术与世界同频。

为了让技术“流动”起来，iia 搭建了多元平台：电子束与 X 射线工作组持续深耕前沿；无菌保障专业人士学会让灭菌科学走进更多实验室与车间；两年一度的国际辐射加工大会（IMRP）更被誉为行业“奥运会”——2024 年刚在哥斯达黎加落幕，2027 年 4 月将移师德国，诚邀各位提前锁定行程；近期，国际辐照协会推出了 HEALTHiiaR 协作平台，致力于推动辐射技术在制药与生物制药领域的应用，欢迎感兴趣的医药界单位和代表的加入。

在 X 射线和医疗应用领域，iia 也多次发布了相关白皮书，早在 2008 年就发布《工业辐照用电子束和 X 射线装置》、2018 年发布《医疗器械和保健产品灭菌用的伽马、电子束、X 射线以及环氧乙烷的对比分析》、2024 年又发布了《建立电子束和 X 射线辐照中心的路线图》并建立了电子束和 X 射线供应商名录等。

回过头我们说为什么众多国际医疗巨头纷纷选择加入 iia？答案很简单：辐照技术是医疗保健产品灭菌的“金钥匙”。从钴-60 伽马到电子束，再到今天的 X 射线，技术迭代从未停歇。今年 4 月，ISO 11137-1:2025 正式发布，X 射线能量阈值由 5 MeV 跃升至 7.5 MeV，穿透力与灭菌效率再上新台阶；伴随国内首台 X 射线辐照装置今年投运、第二台紧锣密鼓调试、后续多台进入招标与商务谈判，中国正式迈入 X 射线辐照商业化元年。此刻召开“中国 X 射线医疗器械灭菌发布会”，可谓恰逢其时。

感谢 IBA 深耕中国市场二十余载，首次聚合法规、设备、服务、终端应用等全产业链顶级伙伴，为行业呈现 X 射线灭菌从标准、装备到商业化落地的完整生态。接下来的主题演讲，将从不同维度解码 X 射线的无限可能，必将为中国医疗健康产业的高质量发展注入“射线级”动能。

预祝各位嘉宾分享精彩纷呈，预祝发布会圆满成功！谢谢大家！

彭伟

国际辐照协会 中国/亚洲代表

2025年9月24日

上海 世博展览馆

Five-Minute Opening Address by Wei Peng, Representing iia, at the “China X-Ray Medical-Device Sterilization Launch” in Medtec China 2025

Ladies and gentlemen, dear colleagues, good afternoon!

It is a great honor to join you at Medtec China 2025, the world-class event for medical-device design and manufacturing, and an even greater privilege to address the “China X-Ray Medical-Device Sterilization Launch” co-hosted by IBA together with Sterigenics, Futeng Irradiation, Johnson & Johnson, BSI and Jiehao Medical.

As the China/Asia Representative of the International Irradiation Association (iia), I extend the Association’s warmest congratulations on the opening of both the exhibition and this launch meeting, and wish every session every success.

The iia is a not-for-profit international organization dedicated to supporting the safe and beneficial use of radiation technology by industry and the scientific community worldwide. Our membership roll reads like a “who’s who” of the sector—today you will see familiar faces such as IBA, Sterigenics and Johnson & Johnson; globally, Abbott, B. Braun, BD, Bayer, Boston Scientific, Cytiva, ICU Medical, Medtronic, SCAPA Health, Sartorius, Smith & Nephew and Wellspect also work hand-in-hand with us.

The iia attaches great strategic importance to China. In 2023 I was appointed as China/Asia Representative; in 2024 we launched iia WeChat and channel, and added the first—non-English area on the iia website. To date, however, no Chinese medical-device company has joined us. We sincerely hope that some of you here will become the “first to eat the crab,” standing shoulder-to-shoulder with global leaders and synchronizing China’s radiation-technology community with the rest of the world.

To keep knowledge flowing, the iia has built multi-layered platforms: the E-beam & X-ray Working Group continues to push the scientific frontier; the Society for Sterility Assurance Professionals brings sterilization science into more labs and plants; and the International Meeting on Radiation Processing (IMRP)—the “Olympics” of our industry—has just concluded in Costa Rica in 2024 and will move to Germany in April 2027; please reserve the dates now. Most recently we launched HEALTHiiaR, a collaboration hub dedicated to radiation applications in pharma and biopharma;

interested partners are warmly invited to join.

In the X-ray and medical field the iia has published a series of white papers: “Industrial Radiation with Electron Beams and X-rays” (2008, iia), “A Comparison of Gamma, E-beam, X-ray and Ethylene Oxide Technologies for the Industrial Sterilization of Medical Devices and Healthcare Products” (2018, iia), and “Roadmap to an Electron Beam or X-ray Center for Industrial Applications” (2024, iia) together with an on-line The Electron Beam and X-ray Supplier Database in iia website.

Why have so many global med-tech giants joined the iia? The answer is simple: radiation technology is the “golden key” to sterilizing health-care products. From cobalt-60 gamma to electron beam and now to X-ray, the technology never stops evolving. In this April, ISO 11137-1:2025 was officially released, raising the X-ray energy threshold from 5 MeV to 7.5 MeV and taking penetration and sterilization efficiency to a new level. With China’s first X-ray irradiator commissioned this year, a second in hot commissioning, and several more in tender or contract negotiation, China has entered the commercial era of X-ray sterilization. Today’s launch meeting could not be more timely.

Thank you, IBA, for your more than twenty years of commitment to China and for bringing together, for the first time, top partners from regulation, equipment, service and end-use to present the full X-ray sterilization ecosystem—from standard to hardware to commercial reality. The keynote speeches that follow will decode the unlimited possibilities of X-ray from multiple angles and inject “radiation-level” momentum into the high-quality development of China’s health-care industry.

I wish every speaker a brilliant presentation and the launch meeting every success. Thank you!

Wei PENG

China/Asia Representative, iia

24 September 2025