NSF PROSYSTEM GmbH
Beim Strohhause 17
20097 Hamburg
Germany

Summary of Qualifications

NSF PROSYSTEM GmbH

NSF PROSYSTEM GmbH is a worldwide leading consulting and service company in biomedical engineering. The company was founded by Prof. Dr. Jürgen Stettin along with his partner Oliver P. Christ in 1999.

The clients of NSF PROSYSTEM GmbH are manufacturers of medical devices, suppliers, external parties, pharmaceutical industry, universities and notified bodies.

NSF PROSYSTEM is an active member in various standardization groups comprising essential standards as ISO 13485, ISO 14971, IEC 62366-1, IEC 60601/61010 and IEC 62304/82304-1.

Our services comprise regulatory affairs, quality management, audits and due diligence, risk management, usability engineering, software development, process control and validation, project management and clinical affairs.

NSF PROSYSTEM is certified according to ISO 9001 and ISO 13485.

PERSONAL DATA

Name	*Lukas Block, M. Sc.*
Position	*Senior Consultant Medical Devices*

ACADEMIC EDUCATION

University	Hamburg University of Applied Sciences Biomedical Engineering
Degree	Master of Science

PROFESSIONAL EXPERIENCE

NSF PROSYSTEM GmbH, Hamburg/Germany (2015 – today)

WORK EXPERIENCE (abstract)

Quality Management	Creation and implementation of Quality Management Systems as well as individual processes (e.g. Risk Management, Usability Engineering, Post-market Surveillance & Post-market Clinical Follow-up, Complaint Handling, Vigilance, Design & Development, etc.) according to ISO 13485:2012, ISO 13485:2016, ISO 9001:2015, Regulation (EU) 2017/745, the Conformity Assessment Procedures of the Australian Therapeutic Goods (Medical Devices) Regulations (TG(MD)R Sch3), Brazilian Good Manufacturing Practices (RDC ANVISA 665/2022), Canadian Medical Devices Regulations, Japan Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and In Vitro Diagnostic Reagents (MHLW Ministerial Ordinance No. 169), the Quality System Regulation (21 CFR 820) Quality Management Representative for NSF PROSYSTEM (ISO 13485:2016 & ISO 9001:2015) Auditing according to ISO 13485, 21 CFR 820, and EU MDR
Regulatory Affairs	Profound knowledge with Directives 93/42/EEC, 98/79/EC, 90/985/EEC, as well as the Regulations (EU) 2017/745 & (EU) 2017/746, 21 CFR 820 QSR

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	Preparation of technical documentations for the conformity assessment in Europe (CE-marking) for class I to class III devices
	Author and reviewer of technical documentations for medical device market clearance according to Medical Device Directive (93/42/EEC) and Regulation (EU) 2017/745
	Implementation of risk management systems according to ISO 14971, ISO/TR 24971, ISO 12100, and for active and non-active medical devices
	Software development projects according to IEC 62304 and IEC 82304 and relevant FDA guidance documents
	Security risk management according to IEC 81001-5-1, AAMI SW 96, and AAMI TIR 57
Clinical Evaluation	Implementation of processes incl. their interfaces for state of the art clinical evaluation
	Author of several Clinical Evaluation Reports (CER) for products of risk classes I, IIa, IIb & III according to MEDDEV 2.7.1 revisions 3/4, incl. research in EMBASE, PubMed, COCHRANE and other clinical experience databases (e.g. for robotic assisted surgery device)
Training Services	Regulation (EU) 2017/745
	EN ISO 13485:2016
	ISO 14971:2019
	Post-market Surveillance according to Regulation (EU) 2017/745
	Clinical Evaluation according to MEDDEV Rev. 4
	Notified Body requirements
Project Management	Team Lead for planning & implementation projects of the Regulation (EU) 2017/745 (e.g. devices for vascular intervention)
	Team Lead for implementation projects of the EN ISO 13485 & Regulation (EU) 2017/745 MDR quality management requirements
	Multiple projects on Regulation (EU) 2017/745 implementation planning, gap identification and closure of identified gaps
	Multiple projects on FDA requirement implementation planning, gap identification and closure of identified gaps
	Design Control projects for medical device software according to Regulation (EU) 2017/745 and EN ISO 13485:2016