

# DIN EN IEC 63077:2024-01 (E)

## Good refurbishment practices for medical imaging equipment (IEC 63077:2019)

---

Contents	Page
European foreword .....	3
Annex ZA (normative) Normative references to international publications with their corresponding European publications .....	4
INTRODUCTION .....	5
1 Scope .....	6
2 Normative references .....	6
3 Terms and definitions .....	7
4 General requirements for REFURBISHMENT of USED MEDICAL IMAGING EQUIPMENT .....	9
4.1 Quality management system .....	9
4.2 Resource management .....	9
4.3 Corrective and preventive action .....	9
4.4 Customer complaints .....	9
4.5 Production and service provision .....	9
4.6 Control of nonconforming PRODUCT .....	10
4.7 Post-market surveillance PROCESS .....	10
4.8 Document control .....	10
4.9 Purchasing .....	10
4.10 Control of design and design changes .....	10
4.11 RISK management PROCESS .....	10
5 Specific requirements for good REFURBISHMENT practice .....	11
5.1 General .....	11
5.2 Selection of MEDICAL IMAGING EQUIPMENT for REFURBISHMENT .....	11
5.3 Evaluating market access requirements .....	11
5.4 Preparation for REFURBISHMENT, disassembly, packing, and transport .....	11
5.5 Planning .....	11
5.6 Installation of software and hardware to ensure the safety of the MEDICAL IMAGING EQUIPMENT .....	12
5.7 Performance and safety test .....	12
5.8 Packing, transport, and installation of refurbished MEDICAL IMAGING EQUIPMENT .....	12
5.9 Record of REFURBISHMENT .....	12
5.10 REFURBISHMENT label .....	12
Annex A (informative) Cross reference list of the contents of IEC 63077 versus ISO 13485 .....	13
Bibliography .....	15
Index of defined terms used in this document .....	16
Tables Table A.1 - Cross reference list of the contents of IEC 63077 versus ISO 13485 .....	13