Medicines & Healthcare products
Regulatory Agency

Manufacturer Incident Report (MIR) - Changelog

Version GB 7.2.1 (04/06/2025)

New fields in XSD

UKABIdNum ("UK Approved Body (UKAB) ID number(s)")
UKABCertNum ("UK Approved Body (UKAB) certificate number(s) of device")
udiIssueEntity ("UDI Issuing entity")

Fields removed in XSD

ncaEudamedNum ("EUDAMED Number of NCA")
refNumEudamed ("Reference number assigned by EUDAMED for this incident")
eudamedRefFSCA ("FSCA EUDAMED reference numbers")

Changes within XSD files

New key <xsd:enumeration value="United Kingdom Responsible Person"/> (Submitter of report)

Removed keys <xsd:enumeration value="EMDN", "UMDNS(ECRI)", "GIVD/EDMS", "Other, please specify"/> (Medical Device terminology used)

key imdrfTypeInvestigationCodeChoice1 (IMDRF Annex B) fix minOccurs="0"
key imdrfInvestigationFindingsCodeChoice1 (IMDRF Annex C) fix minOccurs="0"
key imdrfInvestigationConclusionCodeChoice1,(IMDRF Annex D) fix minOccurs="0"
key imdrfClinicalCodeChoice1 (IMDRF Annex E) fix minOccurs="0"
key imdrfHealthCodeChoice1 (IMDRF Annex F) fix minOccurs="0"
key imdrfComponentCodeChoice1 (IMDRF Annex G) fix minOccurs="0"