



Medicines & Healthcare products Regulatory Agency

Field Safety Corrective Action Report (FSCA) - Changelog

Version GB 2.8 (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")
nbCertNum ("Notified body certificate number")
udiDI ("UDI DI")
udiPI ("UDI PI")
udiDIBasic ("Basic UDI-DI")
udiDIUnitUse ("Unit of use UDI-DI")
udiIssueEntity ("UDI Issuing entity")
imdrfCodeChoice1 (IMDRF Annex A)
imdrfMedicalDeviceProblemMissingDetails
imdrfTypeInvestigationCodeChoice1 (IMDRF Annex B)
imdrfInvestigationTypeMissingDetails
imdrfInvestigationFindingsCodeChoice1 (IMDRF Annex C)
imdrfInvestigationFindingsMissingDetails
imdrfInvestigationConclusionCodeChoice1 (IMDRF Annex D)
imdrfInvestigationConclusionMissingDetails
imdrfClinicalCodeChoice1 (IMDRF Annex E)
imdrfClinicalSignsMissingDetails
imdrfHealthCodeChoice1 (IMDRF Annex F)
imdrfHealthImpactMissingDetails
imdrfComponentCodeChoice1 (IMDRF Annex G)
imdrfComponentMissingDetails
devicesPlacedGB ("The number of devices placed on the market or put into service in Great Britain")
usersAffectedGB ("The estimated number of users affected in Great Britain")

Changes within XSD files

key nbIdNum ("Notified body (NB) ID number(s)") fix type=nbIdNumT

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)