

Common Submission Dossier Template (CSDT)



ASEAN CSDT is document to provide the common template for submission of the medical device information which demonstrate safety and performance to medical device regulatory authorities.

ANNEX 4 ASEAN Common Submission Dossier Template

1. INTRODUCTION

The Common Submission Dossier Template (CSDT) should reduce the differences in documentation formats that presently exist in different ASEAN jurisdictions. The adoption of the CSDT in ASEAN should minimise the preparation of multiple dossiers, arranged in different formats but with essentially the same contents, for regulatory submission to different Regulatory Authorities.

2. SCOPE

This CSDT is intended to apply to all medical devices. For IVD medical devices, the Regulatory Authority of the Member State may choose to adopt this CSDT or prescribe another format for regulatory submissions to that Member States. The depth and detail of the information contained in the CSDT will depend on:

- the classification of the subject medical device;
- the complexity of the subject medical device.

The format of the CSDT recommended herein is based upon the goal of both regulators and product owners to strive for the least burdensome means to demonstrate conformity to the Essential Principles for all classes of medical devices.

Where there are sections not applicable to the medical device, the reason for the non-applicability should be provided under the section heading. Requirements for post-market vigilance or adverse event reporting are outside the scope of this document.