

TECHNICAL FILE

/index.php?q=medicaldevice%2Fform_device&ps=fe&form_id=D2923-20151204-42810



COMMON SUBMISSION DOSSIER TEMPLATE (CSDT) ?

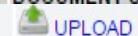
DOCUMENT UPLOAD

PLEASE UPLOAD YOUR CSDT HERE*



SUPPORTING DOCUMENTS FOR COMMON SUBMISSION DOSSIER TEMPLATE (CSDT) ?

DOCUMENT UPLOAD



DEVICE DESCRIPTION*

Please check the box(es) below to indicate that the element(s) has been addressed in the content of supporting document attached

YES NO N/A

Device Description & Features	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Intended use	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Indications	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Instructions of use	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Contraindications	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Warnings	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Precautions	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Potential adverse effects	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Alternative therapy	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Materials	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Other Relevant Specifications	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Other Descriptive Information	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

SUMMARY OF DESIGN VERIFICATION AND VALIDATION DOCUMENTS*



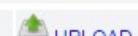
Please check the box(es) below to indicate that the element(s) has been addressed in the content of supporting document attached

YES NO N/A

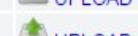
Pre-clinical Studies	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Software Validation Studies	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Devices Containing Biological Material	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Clinical Evidence	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Use of Existing Bibliography	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Sterilization Validation	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Validation For Measuring Function	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

DEVICE LABELLING*

Samples of Labels on the Device and its Packaging



Instructions for Use, Training Materials & Instructions for Installation and Maintenance



RISK ANALYSIS*

Results of Risk Analysis

