

TECHNICAL FILE

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



COMMON SUBMISSION DOSSIER TEMPLATE (CSDT) ?

DOCUMENT UPLOAD

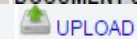
PLEASE UPLOAD YOUR CSDT HERE*



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	
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