1 Location and responsible persons		
1.1. Test or inspection facility (address in full): A person in this facility with responsibility for handling matters related to assessing products under this scheme:		
1.2. Name:		
1.3. Position:		
1.4. Location:		
1.5. Telephone:		
1.6. E-Mail:		
1.7. Fax:		
1.8. This person should have the written authority to represent the organization, enforce the certification body's requirements and make necessary changes in production test facilities and procedures when required by the certification body's standards and related documents.		
1.9. Does this authority exist?	Yes ☐	No ☐
1.10. To whom does this person report? (Name and position)		
1.11. Name of alternative person with the same responsibilities as under 1.1		
2 Production (or supply) facility		
2.1. Name		
2.2. Address		
2.3. A person at a production (or supply) facility with responsibility for product realization assessed under this scheme:		
2.4. Name:		
2.5. Position:		
2.6. Telephone:		
3 Outsourced Process (es)/ Subcontractors using by the client that will affect conformity to requirements		
Are any processes being outsourced?	Yes ☐ No ☐ If yes, please provide the following required information for each subcontractor.	
Subcontractor no. 1:	[Name]	
Address:	[Specify]	

Performed process/(es):	☐ Design and development ☐Purchasing ☐ Production and service provision ☐ Cleanliness of product ☐ Assembly ☐ Packaging and labeling ☐ Servicing activities ☐ Warehouse ☐ Other: [Specify]		
Third-party certification:		Yes ☐	No ☐
4 Quality Management System: (You must attach the certificate and schedules for ISO 9001 certification where obtained. Otherwise, attach quality inspection and test plans used for manufacture.)			
ISO 9001 certification: ☐Yes/☐No	Certification Body		
Certification No. The expiry date of the certification	Date of the last certification		
3.1. The organization has implemented a quality management system following the requirements of EN ISO/IEC 80079-34, ISO 9001, or an equivalent QMS standard.		Yes ☐	No ☐
3.2. The scope of the certification covers the activities of production and/or supply of the category of product for which certification h requested.		Yes ☐	No ☐
5 Personnel			
Append the documentation of the quality management system that specifies the responsibility and authority of all personnel responsible for product design, calibration of measuring devices, verification of incoming products, testing or inspecting products to requirements, and writing product monitoring and measurement records. Please attach the documentation of the required competence for this personnel and the records of their education, training, experience, and skills.			
6 Planning of product realization			
Criteria: The quality management system shall comply with the requirements of EN ISO/IEC 80079-34, ISO 9001 or an equivalent QMS standard (which should be identified).			
5.1. The result of the planning of product realization has been documented.	Yes ☐	No ☐	
5.2. Are there exclusions from the requirements within sub-clauses of ISO/IEC 80079-34, ISO 9001 in the quality management system? If yes, describe the exclusion and its justification.	Yes ☐	No ☐	
7 Customer-related processes			
Criteria: The quality management system shall comply with the requirements of the related sub-clause of ISO/IEC 80079-34, ISO 9001 or an equivalent QMS standard (which should be identified).			
6.1. Is a review conducted before the organization's commitment to supply a product to the customer to ensure that?			

▪ product requirements are defined, ▪ contract or order requirements differing from those previously expressed are resolved, and		
▪ Does the organization have the ability to meet the defined requirements?	Yes ☐	No ☐
6.2. Have records of this review maintained?	Yes ☐	No ☐
6.3. Have records of customers' complaints maintained?	Yes ☐	No ☐
8 Purchasing		
Criteria: The quality management system shall comply with the requirements of ISO/IEC 80079-34, ISO 9001 or an equivalent QMS standard (which should be identified).		
7.1.A record of all verified components containing the following information shall be maintained: a) a description of the component, e.g., switches, relay; b) the name of the supplier; c) the catalog or model designation sufficient to provide specific identification; d) the electrical rating; e) a record of the standards, bulletins, notices, and other requirements used to determine conformity; f) The results of the tests.		
Has this record been maintained? In what form? ..... For how long? ..... Where is it available?	Yes ☐	No ☐
Critical Suppliers		
Are there any suppliers of raw materials, materials, components, or subassemblies that may affect the safety and performance of the device? If yes, please provide the following required information for each critical supplier.	Yes ☐	No ☐
9 Production and service provision		
Criteria: The quality management system shall comply with the requirements of related sub-clauses of ISO/IEC 80079-34, ISO 9001 or an equivalent quality management system standard (which should be identified) if there is no excluded sub-clause with justification		
8.1. Does the product identification apply? If not, please explain.	Yes ☐	No ☐
8.2. How is the monitoring and measurement of product status identified?		
8.3. Does the product traceability apply?	Yes ☐	No ☐
8.4. Does the customer provide any property that is to be incorporated into the final product? If yes, please list them.	Yes ☐	No ☐
8.5. Has a process validation carried out? If yes, please indicate which process and the validation criteria.	Yes ☐	No ☐
10 Control of monitoring and measuring devices		

9.1. What monitoring and measuring equipment is used? List each relevant type by a full description, i.e., measured quantity and serial numbers.		
9.2. At what intervals is each measuring device calibrated?		
9.3. Are written calibration procedures available for each type of measuring device?	Yes ☐	No ☐
9.4. How is the calibration status of measuring devices identified?		
9.5. Are calibration records maintained for each measuring device?	Yes ☐	No ☐
9.6. measuring device marked to show when it was last calibrated?	Yes ☐	No ☐
9.7. What standards are used for calibration? Itemize by model and serial number; indicate when last calibrated and when next due for calibration.		
9.8. Describe how the standards are traced to international or national standards		
9.9. Describe how required environmental conditions that are specified for monitoring and measurement are controlled		
11 Monitoring and measurement of the product		
Criteria: The quality management system shall comply with the requirements of the related sub-clause of ISO/IEC 80079-34, ISO 9001 or an equivalent quality management system standard (which should be identified).		
10.1. A documented monitoring and measurement plan shall be developed which describes all of the production monitoring and measurement necessary to ensure that each product under this product certification scheme complies with the requirements before delivery. This plan shall include details of its implementation as follows: **a)** details of verification controls as applied to incoming materials and components, in-production and final product monitoring and measurement **b)** a system for recording the results of production line monitoring and measurement **c)** details of the methods used for the control of nonconforming products **d)** details of all required monitoring and measurement of the product		
Has been such an inspection and test plans documented? Please attach a copy of this plan	Yes ☐	No ☐
10.2. A list of the characteristics to be inspected and/or tested and the related acceptance criteria shall be available at each location where inspection and/or tests are performed to verify conformance requirements by the EPIL		
Is such information available at these locations?	Yes ☐	No ☐
10.3. Criteria concerning monitoring and measurement product records Monitoring and measurement records that demonstrate the conformance of the final product to the requirements shall include as a minimum: ▪ identification of the product ▪ monitoring and measurement performed ▪ monitoring and measurement results ▪ criteria for acceptance ▪ nonconformities ▪ date of monitoring and/or measurement ▪ person(s) authorizing the release of the product		
Are such records maintained?	Yes ☐	No ☐

Do they contain the information described?	Yes ☐	No ☐
Where are they maintained? ……..		
10.4. Criteria concerning product records The following records shall be maintained for each product under this product certification scheme: a) a copy of the nameplate, nameplate drawing or marker that shows the certification mark, identification number of the product, and the electrical rating b) environmental conditions and results of monitoring and measurement performed on the prototype product to verify conformity to the requirements c) photographs showing external and internal views of the product and its components along with sufficient description, such as drawings and/or text, to provide a record of the initially assessed designs found to comply with the applicable product requirements d) schematic drawings of primary and secondary circuits e) list of primary circuit components, including a description or drawing of the component and relevant test data to demonstrate conformity to the applicable requirements f) list of secondary circuit components that are ▪ in safety circuits, or ▪ not in Class 2 circuits, or ▪ in critical circuits (such as interlock circuits, patient circuits in electro-medical equipment)		
Are such records maintained?	Yes ☐	No ☐
Do they contain the information described?	Yes ☐	No ☐
Who has the authority and responsibility to maintain these records? Name ……. Where are they located? ……..		
12 Control of nonconforming product		
Criteria: The quality management system shall comply with the requirements of related sub-clause of ISO/IEC 80079-34, ISO 9001 or an equivalent quality management system standard (which should be identified).		
11.1. The organization shall establish a documented procedure for the control of nonconforming products.		
Has such a procedure been implemented?	Yes ☐	No ☐
11.2. Components and final products that have been reworked or repaired to comply with the requirements shall be re-verified.		
Is this done?	Yes ☐	No ☐
11.3. Products that bear the EPIL's certification mark and which do not comply with the requirements or have not been covered by the product certification scheme shall have the certification mark removed before they are shipped from the facility**.**		
Is this done?	Yes ☐	No ☐
13 Corrective action		
Criteria: The quality management system shall comply with the requirements of the related sub-clause of ISO/IEC 80079-34, ISO 9001 or an equivalent quality management system standard (which should be identified).		
12.1. The organization shall establish a documented procedure for corrective action. Has such a procedure been implemented**?**	Yes ☐	No ☐

12.2. The product nonconformities shall be investigated to determine the cause. Is this done**?**	Yes ☐	No ☐
12.3. After the cause of nonconformity has been determined, appropriate action shall be taken to avoid repetition. Is this done**?**	Yes ☐	No ☐
12.4. Provide an example of a record of corrective action.		
14 Preventive action		
Criteria: The quality management system shall comply with the requirements of the related sub-clause of ISO/IEC 80079-34, ISO 9001 or an equivalent quality management system standard (which should be identified)		
13.1. The organization shall establish a procedure for preventive action. Has such a procedure been implemented**?**	Yes ☐	No ☐
13.2. Any potential nonconformities of the product should be investigated to determine the cause. Has this been carried out?	Yes ☐	No ☐
13.3. When the cause of a potential nonconformity has been determined, appropriate action should be taken to prevent repetition. Has this been carried out?	Yes ☐	No ☐
13.4. Provide an example of a record of preventive action.		
15 Control of documents		
Criteria: The quality management system shall comply with the requirements of the related sub-clause of ISO/IEC 80079-34, ISO 9001 or an equivalent quality management system standard (which should be identified)		
The organization shall establish a procedure for control of documents Has such a procedure been implemented? Please attach the procedure	Yes ☐	No ☐
16 Control of records		
Criteria: The quality management system shall comply with the requirements of the related sub-clause of ISO/IEC 80079-34, ISO 9001 or an equivalent quality management system standard (which should be identified)		
The organization shall establish a procedure for record control. Has such a procedure been implemented? Please attach the procedure	Yes ☐	No ☐
17 Summary of general details		
Date: ..... Organization's name (in full): ..... Address (in full):		
Production (supply) location name (in full): Address (in full):		

Design, test, and inspection facility (if applicable): Name (in full): ..... Address (in full): .....
Representative responsible for handling matters relating to the EPIL: Representative's name: ..... Position: ..... Location: .....
Category of product manufactured at manufacturing location: