Design Control

This procedure defines the system in use within the company in order to ensure that the design process requirements are planned, controlled and documented.
A portfolio will be created to maintain the documentation for each design. Y-Z It is the responsibility of the Technical Engineer to ensure that this procedure is adhered to, and that any statutory & regulatory requirements are met. It is the responsibility of the Managing Director to ensure that the resources are available to ensure conformity to the above. Final responsibility for the release of new product design or modification lies with the Managing Director or delegated upper management. ID Doc 21556 (ID Doc 2557 original)The organization shall control the design and development of product. As appropriate, design and development planning documents shall be maintained and updated Y as the design and development progresses. Intrastats under x-Projects- Project Product Development Manager,
Requirements for Design Projects Y20 are received from various sources and ideas, such as customer requirements, evolution, market forces etc. Once received, they are then entered as part of the Design Process.
Each new project is entered into Intrastats under x-Projects- Project Product Development Manager, with its own unique Project Heading. At this time such considerations as team members, external interfaces, project timescales Y5 etc. are logged into the program.
With the project open, the Technical Engineer will then start the design process. A folder will be opened in Intrastats with the designated Name of the Project. Within this folder sub folders will be created for each individual aspect of the design.Y-Z All pertinent information through the design process will then be stored in these locations.

During design and development planning, the organization shall document:
the design and development stages Y7 Project Product Development Manager also Y8 ; the review(s) Y16 QC28 needed at each design and development stage; the verification, validation, Y15 and design transfer activities L9 T1 M5 N5 R1 U1 Y11 that are appropriate at each design and development stage; the responsibilities and authorities for design and development J1 ; the methods to ensure traceability of design Y Intrastats under x-Projects- Project Product Development Manager, and development outputs to design and development inputs;Z the resources needed, including necessary competence of personnel. ?

Inputs relating to product requirements Y20 shall be determined and records maintained
These inputs shall include: functional, M3 Performance, Y0 Y1 usability Y3 and safety requirements,according to the intended useE4 ; applicable regulatory requirements and standards C2 ; applicable output(s) of risk management; as appropriate, information derived from previous similar designs; other requirements essential for design and development of the product and processes.

These inputs shall be reviewed for adequacy and approved. Requirements shall be complete, unambiguous, able to be verified or validated, and not in conflict with each other. E4 E5 E11 E3

Design and development outputs shall: meet the input requirements for design and development; Y15 provide appropriate information for purchasing U1 Y17, production and service provision; contain or reference product acceptance criteria; specify the characteristics of the product that are essential for its safe and proper use. The outputs of design and development shall be in a form suitable for verification against the design and development inputs Y15 Z7 and shall be approved prior to release.
Records of the design and development outputs shall be maintained

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned and documented arrangements to Y16 QC24: evaluate the ability of the results of design and development to meet requirements; identify and propose necessary actions. Y16

Participants in such reviews shall include representatives of functions concerned with the design and development stage being reviewed, as well as other specialist personnel.

Records of the results of the reviews and any necessary actions shall be maintained and include the identification of the design under review, the participants involved and the date of the review Y16 QC28

Design and development verification Z7 Y15 shall be performed in accordance with planned and documented arrangements to ensure that the design and development outputs Z7have met the design and development input requirements. Y16 QC28 The organization shall document verification plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size. Y15 If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), verification shall include confirmation that the design outputs meet design inputs when so connected or interfaced. Records of the results and conclusions of the verification and necessary actions shall be maintained

Design and development validation shall be performed in accordance with planned and documented arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use Y15 Y19. The organization shall document validation plans Y15 Y15 that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size. Design validation shall be conducted on representative product. Representative product includes initial production units, batches or their equivalents. The rationale for the choice of product used for validation shall be recorded. As part of design and development validation, the organization shall perform clinical evaluations H3 H4.1 or performance evaluations

of the medical device in accordance with applicable regulatory requirements Z4. A medical device used for clinical evaluation or performance evaluation is not considered to be released for use to the customer.
If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), validation shall include confirmation that the requirements for the specified application or intended use have been met when so connected or interfaced.
Validation shall be completed prior to release for use of the product to the customer. Y15
Records of the results and conclusion of validation and necessary actions shall be maintained H3

The organization shall document procedures for transfer of design and development outputs to manufacturing . These procedures shall ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications and that production capability can meet product requirements. Results and conclusions of the transfer shall be recorded L9 T1 M5 N5 R1 U1 Y11 M4 J9 J3

Finished Design

On completion of the project the Managing director and or an external customer will be given the completed device; the user information specified upon the Design Compliance form; a copy of the Test Schedule indicating the device has met the acceptance criteria for testing J4 . At this stage clinical trials will be undertaken where deemed necessary by the customer or the company in accordance with Annex X MDD. The customer/managing director will signify his acceptance of the product in writing.

Design Changes

The organization shall document procedures to control design and development changes. The organization shall determine the significance of the change to function, performance, usability, safety and applicable regulatory requirements for the medical device and its intended use. Design and development changes shall be identified.
Before implementation, the changes shall be: reviewed; verified; validated, as appropriate; approved.
The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product in process or already delivered, inputs or outputs of risk management and product realization processes. Records of changes, their review and any necessary actions shall be maintained Y14[1]

Design and development files

The organization shall maintain a design and development file for each medical device type or medical device family. This file shall include or reference records generated to demonstrate

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conformity to the requirements for design and development and records for design and development changes.

General Requirements

Products are designed in such a way as to ensure that they cannot compromise the clinical condition or safety of patients, or the health & safety of operators. Products should also conform to the current "State-of-the-art" safety 3585.doc 11/07/2011 Page 1 of 3 principles and legislation, including the provision of alarms where necessary. User operated controls shall be adequate, accessible and clearly defined. All new products must carry the CE mark and comply with all relevant requirements (including EMC testing where appropriate). The design of all medical products should comply with BS EN 60601, IEC 601/1 an other applicable EN standards where possible and shall be in accord with any current relevant Council Directives. Classification of Products will follow the rules and principals of MDD Annex 9. & CMDCAS essential requirements if required.
Products are also designed in such a way that any risk of infection or microbiological contamination is minimal Z6. Any tissue of animal origin must derive from animals that have been subjected to veterinary controls and safeguarded from viral infection Z10. Products will, throughout their design lifetime, under any reasonable environmental and climatic conditions, and under the stress of normal use, always achieve the performance intended and specified. Product characteristics and performances will not be adversely affected by transport or storage.M1:M2; Any undesirable side effect will always constitute an acceptable risk when measured against product performance and benefit to the patient. Acceptability is determined on the basis of both clinical and legal advice. Where any residual risk to either patient or operator is identified, it will be clearly notified to the user. F5 The choice of design materials is determined by environmental and ergonomic considerations; and are, where appropriate, compatible with any biological tissue, cells, body-fluids and other materials with which they will come into contact. Z10 Z11 Z12 Z13 Z6
Devices, which must be used sterile, will be manufactured and sterilized by a validated method and packaged in a non-reusable pack. Those devices which are not sterile will be packaged in such a way that they are kept at a stipulated level of cleanliness. For identical products, in both sterile and non-sterile, then the packaging / labelling of the device will distinguish between these O1 . Devices are designed to minimize or eliminate risks associated with physical features – pressure, weight, environmental conditions, magnetic fields, temperature, reciprocal interference with other devices, deterioration, fire and explosion. Combination of devices to be used together, are designed to be safe and not to impair each other's performance. Devices that have a measuring function will be ergonomically designed and manufactured so as to provide satisfactory accuracy and stability, the limits of which will be specified by the manufacturer, and will conform to the provisions of Directive 80/181/EEC or any later applicable Directive. Any device intended to emit radiation will be designed and manufactured to minimize exposure to patients and users, consistent with its function. The level of output will be controlled with adequate warnings and user instructions. Information provided with the device will be clear and in the form of a label F7 and instructions for

use F5, if possible, on the device itself and / or the packaging. Where possible, by use of: e.g. EN 980, EN1041. All labelling and instructions will have the relevant information as per the requirements of the current MDD. Technical file formats for CE marking are as follows:
a. A Declaration of Conformance for every new or redesigned product.
b. A Technical File Summary for submission to EU notified bodies on request.
c. A full Technical File.
d. A Design File.

Design Files
The full Design file in Electronic format will constitute (as a minimum) the following files:
Test Reports Y18 and Design calculations Y2 Y1
Analysis of complaints / user feedback H1 H2
Clinical Trial Reports H3
Biocompatibility and Toxicity Evaluation
Literature Reviews L1
Compatibility Trials H15 XZ6 Z7
Qualification Test Reports Z2 Z3 Z1 BS11.1 Y18 J4 J6
CE Files
The Technical file summary in Electronic format will constitute (as a minimum) the following files:
EC declaration of conformance. B1
Checklist of the MDD essential requirements and how they are met. C1
Reference to specific documents and / or where they are to be found. A2
Full description of the device with an outline / general assembly drawing if appropriate. F1 M4
Copy of Notified Body Certification B3 B4
Copy of labels and instructions for use F7