Risk Policy Statement

Purpose

To provide guidance for establishing criteria for risk acceptability.

These criteria are used in the evaluation of residual risks associated with the medical devices manufactured by Dynek Pty Ltd.

The criteria will ensure that the medical devices have a high level of safety consistent with stakeholder expectations.

Scope

This policy applies to all persons involved in establishing, reviewing, updating, and approving the criteria for risk acceptability in risk management plans for medical devices designed, developed and/or manufactured by Dynek Pty Ltd for commercial distribution.

Criteria for risk acceptability

The following factors and considerations should be taken into account with establishing the criteria for risk acceptability:

- Applicable regulatory requirements in the regions where the medical device is to be marketed;
- Relevant international standards for the particular type of medical device, including standards for testing specific properties with approval/rejection limits;
- The generally acknowledged *state of the art*, which can be determined form a review of international standards, best practices in technology, results of accepted scientific research, publications from authorities, and other information for similar medical devices and similar other products;
- Validated concerns from stakeholders, for examples obtained through direct communication from users, clinicians, patients or regulatory bodies, or through indirect communication via news reports, social media or patient forums. It is important to consider the perception and understanding of risk acceptability can vary between different groups of stakeholders and can be influenced by their background and the nature of their interest.

Approaches to risk control

The general approach that is used by Dynek is to reduce risk as far as possible without adversely affecting the benefit-risk ratio.

Consideration is given to whether technically practicable measures would reduce the risk without impacting the intended use or the benefit of the medical device.

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Date: 31/01/2022