Risk Management System

A few definitions are necessary to start understanding.

Benefit-risk determination means the analysis of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the intended purpose given by the manufacturer

Clinical benefit means the positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis, or a positive impact on patient management or public health

Risk means the combination of the probability of occurrence of harm and the severity of that harm

RMS and QMS
Article 10 General Obligations of Manufacturers requires the manufacturer to establish, document, implement, and maintain a risk management system, RMS, as described in Annex I, Section 3. In addition, it requires that manufacturers of devices, other than investigational devices, establish, document, implement, maintain, keep up to date, and continually improve a quality management system, QMS.

The QMS must address risk management as set out in in Section 3 of Annex I.

MDR Annex I, Section 3
Manufacturers establish, implement, document, and maintain a risk management system, RMS, which is a continuous iterative process throughout the entire lifecycle of a device. The RMS requires regular systematic updates.

The RMS includes specific elements.

- Establish and document a risk management plan for each device.
- Identify and analyze the known and foreseeable hazards associated with each device.
- Estimate and evaluate the risk for both the intended use and the reasonably foreseeable misuse.
- Eliminate or control these risks following MDR Annex I, Section 4
- Evaluate the impact from both production and the post-market surveillance system, PMSS, on:
    - Hazards
    - The frequency of occurrence of hazards
    - Risk estimates associated with the hazards
    - The overall risk
    - The risk benefit ratio
    - Risk acceptability
- Amend risk control measures, as necessary, based on the evaluation of the impact of the information.

MDR Annex I, Sections 4 and 5
Risk control measures for the design and manufacture of devices must conform to safety principles, takin into account the generally acknowledged state of the art.

Manage risks so that the residual risk for each hazard is acceptable. (Residual risk is the risk remaining after implementing the risk control measures; see ISO 14971:2007 Clause 2.15.) In addition, the overall residual risk for the device is acceptable.

Select the risk control in the following priority order:

- Eliminate or reduce risks as far as possible through safe design and manufacture.
- Take adequate protection measures, including alarms if necessary, for any risks that cannot be eliminated.
- Provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users.

For the elimination or reduction of risks associated with use errors:

- Reduce, as far as possible, the risks related to the ergonomic features of the device
- Reduce, as far as possible, the risks related to the environment in which the device is intended to be used (design for patient safety).
- Consider the technical knowledge, experience, education, training, and use environment of the intended users.
- Consider the medical and physical conditions of intended users (design for lay, professional, disabled, or other users).

Inform users of any residual risks.

Recommendations for Manufacturers
EN ISO 14971:2012 is the standard harmonized to the Medical Device Directive, MDD, through seven content deviations. Recognize that there will be a new EU version, probably EN ISO 14971:2017, harmonized to the MDR.

Be sure the risk management file is up to date.

Many people misread MDD Content Deviation #7, believing that information for safety is not a risk control measure. Notice that in the MDR priority order information for safety is the third item on the list.

MDD Content Deviation #7 said that disclosure of residual risk doesn't provide further risk reduction. This remains true, and the MDR requires to manufacturer to inform users of any residual risk.