

Risk Management Policy & Definitions.

Viamed Policy on Risk Management.

Annex I, paras 1, 2 & 6 of the MDD/93/42 address risk management.

1. Definitions of hazard severity and event probability are :

Rating.	Hazard severity.	Event probability.
1	Insignificant.	Improbable.
2	Tolerable.	Occasional.
3	Critical.	Likely.
4	Intolerable.	Highly likely.

2. Solutions are implemented to reduce hazard severity from level 4 (intolerable) identified at the conceptual stage to level 2 (tolerable) or lower.

If hazard severity cannot be reduced from level 4 (intolerable), the product is abandoned.

3. Hazard severity and event probability which cannot be reduced from level 3 (critical) and level 3 (likely) / level 4 (highly likely) respectively are reviewed by the MD and either:

- i. Signed off if considered acceptable when weighed against the benefits.
- ii. The product abandoned if not.

4. Effectiveness of implemented risk management solutions is implied by a reduction in ratings.

5. The overall risk rating formed by the product of hazard severity x event probability cannot alone be the deciding factor of whether product development continues or is abandoned; a low risk occurring regularly would be considered less serious than a high risk occurring occasionally.

6. See below for action taken for hazard severity x event probability combinations:

Hazard severity	Event probability	Risk product	Level of risk	Action taken
1	1	1	Low ↓ High	No further action.
1	2	2		No further action.
2	1	2		No further action.
2	2	4		No further action.
1	3	3		Reduce event probability or MD review of benefit to risk.
3	1	3		Reduce hazard severity or MD review of benefit to risk.
1	4	4		Reduce event probability or MD review of benefit to risk.
2	3	6		Reduce event probability or MD review of benefit to risk.
3	2	6		Reduce hazard severity or MD review of benefit to risk.
2	4	8		Reduce event probability or MD review of benefit to risk.
3	3	9		Reduce hazard severity or MD review of benefit to risk.
3	4	12		Reduce event probability or MD review of benefit to risk.
4	1	4	Intolerable	Reduce hazard severity or abandon the product.
4	2	8	Intolerable	Reduce hazard severity or abandon the product.
4	3	12	Intolerable	Reduce hazard severity or abandon the product.
4	4	16	Intolerable	Reduce severity of hazard or abandon the product.

7. Risk analysis / management is reviewed periodically to ensure safety of products & users.