



Joint Industry Recommendation

Guidance on the applicability of EHSR of the Machinery Directive (2006/42/EC) to Medical Devices

1. Purpose of this Recommendation

Medical devices that are also machinery shall also meet the Essential Health & Safety Requirements (EHSR) of the Machinery Directives (2006/42/EC; MD) to the extent to which those EHSRs are more specific than the Essential Requirements (ER) set out in Annex I of the Medical Devices Directive (93/42/EEC as amended by 2007/47/EC; MDD).

The purpose of this recommendation is to provide guidance which essential health & safety requirements (EHSR) of the machinery directive (2006/42/EC) are considered more specific and therefore have to be addressed by medical devices, which also meet the definition of machinery.

2. Introduction

Some clarifications have been given in the Interpretative Fiche posted on the Website of the European Commission:

http://ec.europa.eu/enterprise/medical_devices/guide-stds-directives/interpretative_fiche_machinery.pdf

- “Only a single conformity assessment is required, under the Medical Devices Directive, for medical devices that are also machinery”
- “The Risk Assessment to be carried out for medical devices that are also machinery is the risk/benefit analysis according to the Medical Devices Directive (MDD, 93/42/EEC Annex I, requirement 1)”

Risk Assessment as stated in the second bullet refers to the full risk management process as described in EN 14971, harmonized under the 93/42/EEC (MDD), with regards to the risk/benefit approach specified in Annex I, Essential Requirement 2. of the MDD.

This implies that the residual risk for the EHSRs from the Machinery Directive is also acceptable when justified by the benefit for the patient: The Risk Management approach described in the MDD Annex I, essential requirement 2. prevails in such case over EHSR of the machinery Directive.

The following table lists the EHSRs from Machinery Directive and whether they are considered applicable or not for medical devices that are also machinery.

EHSR is considered as applicable for medical devices when the hazard is relevant and not explicitly covered by the essential requirements in the MDD; i.e. the EHSR from the machinery directive is more specific than the ER of the medical device directive and therefore has to be addressed by those medical devices that are also machinery. However, this EHSR may be addressed by the application of harmonized standards of the MDD as identified in the column “Rationale”.

Yes = EHSR more specific than ER/no ER

In the table, EHSR is considered as not applicable for medical devices, when the corresponding hazard is not relevant for medical devices, or when the MDD essential requirements already sufficiently cover the corresponding hazard.

No = EHSR not relevant/sufficiently covered by ER

3. Table

EHSR of MD 2006/42/EC		Applicable to medical devices Yes/No	Rationale
1	ESSENTIAL HEALTH AND SAFETY REQUIREMENTS	No	Title only
1.1	GENERAL REMARKS	No	Title only
1.1.1	Definitions	Yes	Defined terms necessary for understanding EHSR of MD
1.1.2.	Principles of safety integration	No	Principles of safety integration specific to medical devices described in MDD Annex I, ER 1,2,3, 4, 5 and EN14971
1.1.3.	Materials and products	No	Covered by MDD Annex I, ER 7
1.1.4.	Lighting	Yes	To be addressed by EN14971 and in some cases portions of EN 60601-1;3 rd ed.
1.1.5	Design of machinery to facilitate its handling	No	Covered by MDD Annex I, ER 5 and EN14971, Annex E,H
1.1.6	Ergonomics	No	Covered by MDD Annex I, ER 1 and EN14971, EN60601-1-6, EN 62366 (to be harmonized soon)
1.1.7.	Operating positions	No	Covered by MDD Annex I, ER 7, 9, 11
1.1.8	Seating	Yes	Only partially covered by MDD Annex I, ER 1, 9, ER 12.7.2. This requirement is applicable when the operating position is an integral part of the machinery. This requirement is not relevant for seats used in work station environment like PACS or control work station
1.2	CONTROL SYSTEMS	No	Title only
1.2.1	Safety and reliability of control systems	No	Covered by MDD Annex I, ER 12.1, 12.9 and EN60601-1-4
1.2.2.	Control devices	Yes	Only partially covered by MDD Annex I, ER 12, ER 12.9 and EN6061-1-6, EN 14971, and some particular standards (e.g. EN60601-2-32) Double command not allowed by MD (except for stop controls and emergency stops) – to be addressed by EN 14971.
1.2.3	Starting devices	No	Covered by MDD Annex I, ER 12., EN 60601-1 ¹
1.2.4	Stopping	No	Title only
1.2.4.1	Normal Stop	No	Covered by MDD Annex I, ER 12
1.2.4.2	Operational Stop	No	Covered by MDD Annex I, ER 12.
1.2.4.3	Emergency Stop	No	Covered by MDD Annex I, ER 12.1, 12.2
1.2.4.4	Assembly of machinery	No	Covered by MDD Annex I, ER 12., EN 60601-1
1.2.5	Selection of control or operating modes	No	Covered by MDD Annex I, ER 12., EN 60601-1, EN 14971
1.2.6	Failure of the power supply	No	Covered by MDD Annex I, ER 12.1, 12.3, EN 60601-1, EN 60601-1-2, EN 14971
1.3	PROTECTION AGAINST MECHANICAL HAZARDS	No	Title only
1.3.1	Risk of loss of stability	No	Covered by MDD Annex I, ER 9, 12.7.1 and EN 60601-1
1.3.2	Risk of break-up during operation	No	Covered by MDD Annex I, ER 9, 12.7.1, 13.6 (d) and EN 60601-1
1.3.3	Risks due to falling or ejected objects	No	Covered by ER 9, 12 and EN 60601-1
1.3.4	Risks due to surfaces, edges or angles	No	Covered by MDD Annex I, ER 9, 12.7.1 and EN 60601-1
1.3.5	Risks related to combined machinery	No	Not relevant - medical devices are no combined machinery in the sense of this sub-chapter
1.3.6	Risks related to variations in operating conditions	No	Covered by ER 12.9
1.3.7	Risks related to moving parts	No	Covered by MDD Annex I, ER 9.2, 12.7.1, 13.6 and EN 60601-1 , and some particular (e.g. EN 60601-2-32)
1.3.8	Choice of protection against risks arising from moving parts	No	Explanatory text
1.3.8.1	Moving transmission parts	No	Covered by MDD Annex I, ER 9.2, 12.7.1 and EN 60601-1
1.3.8.2	Moving parts involved in the process	No	Covered by MDD Annex I, ER 9.2, 12.7.1 and EN 60601-1
1.3.9	Risks of uncontrolled movements	No	Covered by MDD Annex I, ER 12.7.1, EN 60601-1, and some particular (e.g. EN 60601-2-32)
1.4	REQUIRED CHARACTERISTICS OF GUARDS AND PROTECTIVE DEVICES	No	Title only
1.4.1	General requirements	No	Covered by MDD Annex I, ER 9.2, 12.7.1 and EN 60601-1, EN14971
1.4.2	Special requirements for guards	No	Covered by MDD Annex I, ER 9.2, 12.7.1 and EN 60601-1 EN14971
1.4.2.1	Fixed guards	No	Covered by MDD Annex I, ER 9.2, 12.7.1 and EN 60601-1, EN14971
1.4.2.2	Interlocking movable guards	No	Covered by MDD Annex I, ER 9.2, 12.7.1 and EN 60601-1, EN14971

¹ Reference to EN 60601-1 includes reference to collateral and particular standards of this series where applicable. This reference is additionally a wild-card for references to other EN ISO/EN collateral and particular device specific standards where applicable.

EHSR of MD 2006/42/EC	Applicable to medical devices Yes/No	Rationale
1.4.2.3 Adjustable guards restricting access	No	Covered by MDD Annex I, ER 9.2, 12.7.1 and EN 60601-1 ¹ , EN14971
1.4.3 Special requirements for protective devices	No	Covered by MDD Annex I, ER 9.2, 12.7.1 and EN 60601-1, EN14971
1.5 RISKS DUE TO OTHER HAZARDS	No	Title only
1.5.1 Electricity supply	No	Covered in MDD Annex I ER 12 and EN 60601-1
1.5.2 Static electricity	No	Covered in MDD Annex I ER 9.2 and EN 60601-1
1.5.3 Energy supply other than electricity	No	Covered in MDD Annex I ER 12 and EN 60601-1
1.5.4 Errors of fitting	Yes	Only partially covered by MDD Annex I ER9.1, ER12.7.4 and in EN14971, EN 62366 and specific standards (e.g. EN13014, EN20594, EN 5359, EN 5360, regarding connectors)
1.5.5 Extreme temperatures	No	Covered in MDD Annex I ER 9.2, 12.7.5 and EN 60601-1
1.5.6 Fire	No	Covered in MDD Annex I ER 9.3 and EN 60601-1
1.5.7 Explosion	No	Covered in MDD Annex I ER 9.3 and EN 60601-1
1.5.8 Noise	No	Covered in MDD Annex I ER 12.7.3 and EN 60601-1
1.5.9 Vibrations	No	Covered in MDD Annex I ER 12.7.2 and EN 60601-1
1.5.10 Radiation	No	Covered in MDD Annex I ER 11, ER 12.5 and EN 60601-1, and EN 14971
1.5.11 External radiation	No	Covered in MDD Annex I ER 9.2 and EN 60601-1
1.5.12 Laser radiation	No	Covered in MDD Annex I ER 11 and EN 60601-1
1.5.13 Emissions of hazardous materials and substances	No	Covered in MDD Annex I ER 7.1, 7.3, 7.5
1.5.14 Risk of being trapped in a machine	No	Covered in MDD Annex I ER 9.2, 12.7 and EN 60601-1
1.5.15 Risk of slipping, tripping or falling	No	Not relevant
1.5.16 Lightning	No	Covered in MDD Annex I ER 9.2, 12.6 and EN 60601-1
1.6. MAINTENANCE	No	Title only
1.6.1 Machinery maintenance	Yes	Only partially Covered in MDD Annex I ER 4, 13.6d, apply EN 60601-1 and EN14971
1.6.2. Access to operating positions and servicing points	Yes	Only partially Covered in MDD Annex I ER 4, 13.6d, apply EN 60601-1 and EN14971
1.6.3. Isolation of energy sources	Yes	Only partially Covered by MDD Annex I, ER 12.2, ER13.6d, apply EN 60601-1 and EN14971
1.6.4. Operator intervention	No	Covered in MDD Annex I ER 12.7.4, 12.9, 13.6d
1.6.5. Cleaning of internal parts	No	Covered in MDD Annex I ER 7
1.7. INFORMATION	No	Title only
1.7.1. Information and warnings on the machinery	No	Covered in MDD Annex I ER 11.4, 12.9, 13.1, 13.2
1.7.1.1 Information and information devices	No	Covered in MDD Annex I ER 11.4, 12.9, 13.1, 13.2, 13.6
1.7.1.2 Warning devices	No	Covered in MDD Annex I ER 2, 11.4, 12.3, 12.4, 13.2
1.7.2. Warning of residual risks	No	Covered in MDD Annex I ER 2, 11.4, 12.9,13
1.7.3. Marking of machinery	No	Covered in MDD Annex I ER 13.3
1.7.4. Instructions	No	Covered in MDD Annex I ER 13
1.7.4.1 General principles for the drafting of instructions	No	Covered in MDD Annex I ER 13, EN 60601-1 and -1-6, EN 1041, EN14971
1.7.4.2 Contents of the instructions	No	Covered in MDD Annex I ER 13.6, EN 60601-1 and EN 1041, EN14971
1.7.4.3 Sales literature	No	Covered by MDD Article 1 g) and Annex I, ER 4, 13
2 SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR CERTAIN CATEGORIES OF MACHINERY	No	Title and explanatory text only
2.1 FOODSTUFFS MACHINERY AND MACHINERY FOR COSMETICS OR PHARMACEUTICAL PRODUCTS	No	Not relevant for medical devices
2.2 PORTABLE HAND-HELD AND/OR HAND-GUIDED MACHINERY	No	Title only
2.2.1 General	No	Covered in MDD Annex I ER 9, 12
2.2.1.1 Instructions	No	Covered in MDD Annex I ER 13.6
2.2.2 Portable fixing and other impact machinery	No	Not relevant
2.3 MACHINERY FOR WORKING WOOD AND MATERIAL WITH SIMILAR PHYSICAL CHARACTERISTICS	No	Not relevant
3 SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET HAZARDS DUE TO THE MOBILITY OF MACHINERY	No	Title and explanatory text only

¹ Reference to EN 60601-1 includes reference to collateral and particular standards of this series where applicable. This reference is additionally a wild-card for references to other EN ISO/EN collateral and particular device specific standards where applicable.

EHSR of MD 2006/42/EC		Applicable to medical devices	Rationale
		Yes/No	
3.1	GENERAL	No	Title only
3.1.1	Definitions	Yes	Defined terms necessary for the understanding
3.2	WORK POSITIONS	No	Title only
3.2.1	Driving Position	No	Covered in MDD Annex I ER 2, 4, 9
3.2.2	Seating	No	Not relevant
3.2.3	Positions for other persons	No	Covered in MDD Annex I ER 2, 4, 9
3.3	CONTROL SYSTEMS	No	Covered in MDD Annex I ER 2, 4, 9, 12.9 and EN 60601-1 ¹ , EN 14971
3.3.1	Control devices	No	Covered in MDD Annex I ER 2, 4, 9, 12.9 and EN 60601-1, EN 14971
3.3.2	Starting/moving	No	Covered in MDD Annex I ER 2, 4, 9 and EN 60601-1, EN 14971
3.3.3	Travelling function	No	Covered in MDD Annex I ER 2, 4, 9 and EN 14971
3.3.4	Movement of pedestrian-controlled machinery	No	Covered in MDD Annex I ER 2, 4, 9 and EN 60601-1, EN 14971
3.3.5	Control circuit failure	No	Covered in MDD Annex I ER 2, 4, 9 and EN 60601-1, EN 14971
3.4	PROTECTION AGAINST MECHANICAL HAZARDS	No	Title only
3.4.1	Uncontrolled movements	No	Covered in MDD Annex I ER 2, 4, 9, 12.7.1 and EN 60601-1, EN 14971
3.4.2	Moving transmission parts	No	Covered in MDD Annex I ER 2, 4, 9, 12.7.1 and EN 60601-1, EN 14971
3.4.3	Roll-over and tip-over	No	Covered in MDD Annex I ER 2, 4, 9 and EN 14971
3.4.4	Falling objects	No	Not relevant
3.4.5	Means of access	Yes	Only partially covered in MDD Annex I ER 2, 4, 9 and EN 60601-1, EN 14971
3.4.6	Towing devices	No	Not relevant
3.4.7	Transmission of power between self-propelled machinery (or tractor) and recipient machinery	No	Not relevant
3.5	PROTECTION AGAINST OTHER HAZARDS	No	Title only
3.5.1	Batteries	No	Covered in MDD Annex I ER 2, 4, 7.5, 9, 12.6, 12.7.1 and EN 60601-1, EN 14971
3.5.2	Fire	No	Covered in MDD Annex I ER 2, 4, 9.3 and EN 60601-1, EN 14971
3.5.3	Emissions of hazardous substances	No	Covered in MDD Annex I ER 2, 4, 7.5, 9.3 and EN 60601-1, EN 14971
3.6	INFORMATION AND INDICATIONS	No	Title only
3.6.1	Signs, signals and warnings	No	Covered in MDD Annex I ER 2, 4, 9, 13 and EN 60601-1, EN 14971
3.6.2	Markings	Yes	Not covered in MDD; necessary only for those devices defined in MD EHSR 3.1.1
3.6.3	Instructions	No	Title only
3.6.3.1	Vibrations	No	Covered in MDD Annex I ER 9, 12.7.2, 13 and EN 60601-1, EN 14971
3.6.3.2	Multiple uses	No	Covered in MDD Annex I ER 13.6 (c)
4	SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET HAZARDS DUE TO LIFTING OPERATIONS	No	Title and explanatory text only
4.1.	GENERAL	No	Title only
4.1.1.	Definitions	Yes	Defined terms necessary for the understanding
4.1.2.	Protection against mechanical hazards	No	Title only
4.1.2.1	Risks due to lack of stability	No	Covered by MDD Annex I, ER 5, 9, 12.7.1 and EN 60601-1, EN 14971
4.1.2.2	Machinery running on guide rails and rail tracks	No	Covered by MDD Annex I, ER 2, 9, 12.7.7 and EN 60601-1, EN 14971
4.1.2.3	Mechanical strength	No	Covered by MDD Annex I, ER 4, 5, 7.1, 9, 12.7.1 and EN 60601-1, EN 14971
4.1.2.4	Pulleys, drums, wheels, ropes and chains	No	Covered by MDD Annex I, ER 4, 9, 12.7.1 and EN 60601-1, EN 14971
4.1.2.5	Lifting accessories and their components	No	Covered by MDD Annex I, ER 4, 9, 12.7.1 and EN 60601-1, EN 14971
4.1.2.6	Control of movements	No	Covered by MDD Annex I, ER 4, 9, 12.7.1 and EN 60601-1, EN 14971
4.1.2.7	Movements of loads during handling	No	Covered by MDD Annex I, ER 2, 4, 9, 12.7.1 and EN 60601-1, EN 14971

¹ Reference to EN 60601-1 includes reference to collateral and particular standards of this series where applicable. This reference is additionally a wild-card for references to other EN ISO/EN collateral and particular device specific standards where applicable.

EHSR of MD 2006/42/EC	Applicable to medical devices Yes/No	Rationale
4.1.2.8 Machinery serving fixed landings	No	Not relevant
4.1.3. Fitness for purpose	No	Covered by MDD Annex I, ER 3 and also by EN60601-1 and EN 60601-1-6.
4.2. REQUIREMENTS FOR MACHINERY WHOSE POWER SOURCE IS OTHER THAN MANUAL EFFORT	No	Title only
4.2.1. Control of movements	No	Covered by MDD Annex I, ER 4, 9, 12.7.1 and EN 60601-1 ¹ , EN 14971 and particular standards (e.g. EN60601-2-32)
4.2.2. Loading control	No	Not relevant
4.2.3. Installations guided by ropes	No	Not relevant
4.3. INFORMATION AND MARKINGS	No	No spec, title
4.3.1. Chains, ropes and webbing	No	Covered by MDD Annex I, ER 13.3, 13.5
4.3.2. Lifting accessories	No	Covered by MDD Annex I, ER 13.3, 13.5
4.3.3. Lifting machinery	No	Covered by MDD Annex I, ER 13.3, 13.5
4.4. INSTRUCTIONS	No	Title only
4.4.1. Lifting accessories	No	Covered by MDD Annex I, ER 13.5, 13.6
4.4.2. Lifting machinery	No	Covered by MDD Annex I, ER 13.5, 13.6
5 SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY INTENDED FOR UNDERGROUND WORK	No	Whole chapter not relevant for medical devices
6 SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY PRESENTING PARTICULAR HAZARDS DUE TO THE LIFTING OF PERSONS	No	Title and explanatory text only
6.1. GENERAL	No	Title only
6.1.1. Mechanical strength	No	Covered in MDD Annex I ER 9, 12.7.1 and EN 60601-1, EN 14971 General rule of EHSR: safety factors of MD EHSR 4.1.2.4 and 4.2.2.5 are doubled; When particular rules exist in particular standards they shall prevail (e.g. in EN60601-2-32 the working factor can be reduced from 4 to 2.5)
6.1.2. Loading control for machinery moved by power other than human strength	No	Not relevant
6.2. CONTROL DEVICES	No	Covered by MDD Annex I ER 12.7 and EN 60601-1, EN 14971, and particular standards (e.g. EN60601-2-32)
6.3. RISKS TO PERSONS IN OR ON THE CARRIER	No	Title only
6.3.1. Risks due to movements of the carrier	No	Covered by MDD Annex I ER 2, 9.2, 12.7 and EN14971
6.3.2. Risk of persons falling from the carrier	No	Covered by MDD Annex I ER 2, 9.2, 12.7 and EN14971
6.3.3. Risk due to objects falling on the carrier	No	Not relevant
6.4. MACHINERY SERVING FIXED LANDINGS	No	Whole chapter not relevant
6.5. MARKINGS	No	Covered by MDD Annex I, ER 13.3

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