

COCIR Recommendation

Applicability of EHSR of the Machinery Directive (2006/42/EC) to Medical Devices

1. Purpose of this Recommendation

According to MDR Article 1 (12), medical devices that are also machinery shall also meet the Essential Health & Safety Requirements (EHSR) of the Machinery Directive (2006/42/EC; MD) to the extent to which those EHSRs are more specific than the General Safety & Performance Requirements (GSPR) set out in Annex I of the Medical Device Regulation (EU 2017/745).

The purpose of this recommendation¹ is to provide guidance which EHSR of the Machinery Directive are considered more specific and therefore have to be addressed by medical devices, which also meet the definition of machinery.

Note: The Directive requires to assess clauses that are considered “more specific” and not “more detailed”.

2. Introduction

Some clarifications have been provided by the European Commission in the guide to application of the Machinery Directive².

- “In accordance with Article 3, the MD is thus not applicable to machinery that is within the scope of the MDD.”
- “It should be noted that Article 3 of the MDD as amended makes any essential health and safety requirements of the MD that are relevant and that are more specific than the ones included in the MDD applicable to medical devices that are machinery, while all the other obligations relating to the placing on the market of such devices, including the conformity assessment procedure and the risk assessment, are set by the MDD only.”

In addition, the 2009 interpretative document³ explains that the risk assessment to be carried out for medical devices that are also machinery is the risk/benefit analysis as set out in the essential requirements of the Directives concerning medical devices.

Note: In view of the up-coming Date of Application of the MDR, these guidance documents need to be updated.

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

Yes = EHSR more specific than GSPR or has no corresponding GSPR

An EHSR is considered applicable to medical devices when the hazard is relevant and not explicitly covered by the GSPR of the MDR; i.e. the EHSR is more specific than the GSPR. This ESHR therefore has to be addressed by those medical devices that are also machinery.

No = EHSR not relevant or is sufficiently covered by GSPR

In the table, an EHSR is considered not applicable to medical devices, when the corresponding hazard is not relevant for medical devices, or when the GSPR of the MDR already sufficiently covers the corresponding hazard.

¹ This document follows up on our 2008 recommendation for the Medical Device Directive, http://cocir.org/fileadmin/Position_Paper_2008/joint_guidance_ehsr_applicable_to_med_devices_30_November_2008.pdf

² Guide to the Application of the Machinery Directive, 1 July 2017, <https://ec.europa.eu/docsroom/documents/24722/attachments/1/translations/en/renditions/pdf>

³ Interpretation of the relation between the revised Directives 90/385/EEC and 93/42/EEC concerning (active implantable) medical devices and Directive 2006/42/EC on machinery <http://ec.europa.eu/DocsRoom/documents/10261/attachments/1/translations/en/renditions/native>

3. Comparison table

EHSR of MD 2006/42/EC		Applicable requirement to medical devices (Yes/No)	Rationale: ER in MDD	GSPR in MDR
M1	ESSENTIAL HEALTH AND SAFETY REQUIREMENTS	No	N/A (title only)	N/A (title only)
1.1	GENERAL REMARKS	No	N/A (title only)	N/A (title only)
1.1.1	Definitions	No	N/A (definition only)	N/A (definition only)
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	Covered by GSPR 1, 2, 3, 4, 5
1.1.3.	Materials and products	No	Covered by MDD Annex I, ER 7	Covered by GSPR 10
1.1.4.	Lighting	Yes	To be addressed by EN14971 and in some cases portions of EN 60601-1;3rd ed.	Partially covered by GSPR 17.3 for mobile computing platforms
1.1.5	Design of machinery to facilitate its handling	No	Covered by MDD Annex I, ER 5 and EN14971, Annex E,H	Covered by GSPR 3, 5, 7
1.1.6	Ergonomics	No	Covered by MDD Annex I, ER 1 and EN14971, EN60601-1-6, EN 62366 (to be harmonized soon)	Covered by GSPR 1, 3, 5, 14.2, 14.6
1.1.7.	Operating positions	No	Covered by MDD Annex I, ER 7, 9, 11	Covered by GSPR 10, 11, 14, 16, 18, 20
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	Partially covered by GSPR 1, 2, 3, 5, 14, 20.2 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	N/A (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	GSPR 10.1, 14, 17, 18, 20, 21.3
1.2.2.	Control devices	Yes	Only partially covered by MDD Annex I, ER 12, ER 12.9 and EN6061-1-6, EN ISO 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 ISO 14971.	Partially covered by GSPR 14, 17, 18, 20 and 21.3 Double command not allowed by MD (except for stop controls and emergency stops) – to be addressed by EN ISO 14971.
1.2.3	Starting devices	No	Covered by MDD Annex I, ER 12., EN 60601-1	Covered by GSPR 14, 17, 18, 21, 20

EHSR of MD 2006/42/EC		Applicable requirement to medical devices (Yes/No)	Rationale: ER in MDD	GSPR in MDR
1.2.4	Stopping	No	N/A (title only)	N/A (title only)
1.2.4.1	Normal Stop	No	Covered by MDD Annex I, ER 12	Covered by GSPR 17, 18, 21
1.2.4.2	Operational Stop	No	Covered by MDD Annex I, ER 12.	Covered by GSPR 17, 18, 21
1.2.4.3	Emergency Stop	No	Covered by MDD Annex I, ER 12.1, 12.2	Covered by GSPR 17, 18, 21
1.2.4.4	Assembly of machinery	No	Covered by MDD Annex I, ER 12., EN 60601-1	Covered by GSPR 17, 18, 21
1.2.5	Selection of control or operating modes	No	Covered by MDD Annex I, ER 12., EN 60601-1, EN ISO 14971	Covered by GSPR 3, 17, 18, 21
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 ISO 14971	Covered by GSPR 3, 17, 18.1, 18.2, 18.3, 20
1.3	PROTECTION AGAINST MECHANICAL HAZARDS	No	N/A (title only)	N/A (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	Covered by GSPR 7, 14.2(g), 20.1
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	Covered by GSPR 14.2(g), 10.1, 20.1, 23.4(k)
1.3.3	Risks due to falling or ejected objects	No	Covered by ER 9, 12 and EN 60601-1	Covered by GSPR 14, 20
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	Covered by GSPR 14, 20.1
1.3.5	Risks related to combined machinery	No	Not relevant - medical devices are no combined machinery in the sense of this sub-chapter	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	Covered by GSPR 21.3
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)	Covered by GSPR 14.2, 20.1, 23.4
1.3.8	Choice of protection against risks arising from moving parts	No	N/A (Explanatory text)	N/A (Explanatory text)

EHSR of MD 2006/42/EC		Applicable requirement to medical devices (Yes/No)	Rationale: ER in MDD	GSPR in MDR
1.3.8.1	Moving transmission parts	No	Covered by MDD Annex I, ER 9.2, 12.7.1 and EN 60601-1	Covered by GSPR 14.2, 20.1
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	Covered by GSPR 14.2, 20.1
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)	Covered by GSPR 1720.1
1.4	REQUIRED CHARACTERISTICS OF GUARDS AND PROTECTIVE DEVICES	No	N/A (title only)	N/A (title only)
1.4.1	General requirements	No	Covered by MDD Annex I, ER 9.2, 12.7.1 and EN 60601-1, EN14971	Covered by GSPR 3, 14.2, 18, 20.1
1.4.2	Special requirements for guards	No	Covered by MDD Annex I, ER 9.2, 12.7.1 and EN 60601-1 EN14971	Covered by GSPR 3, 14.2, 20.1
1.4.2.1	Fixed guards	No	Covered by MDD Annex I, ER 9.2, 12.7.1 and EN 60601-1, EN14971	Covered by GSPR 3, 14.2, 20.1
1.4.2.2	Interlocking movable guards	No	Covered by MDD Annex I, ER 9.2, 12.7.1 and EN 60601-1, EN14971	Covered by GSPR 3, 14.2, 20.1
1.4.2.3	Adjustable guards restricting access	No	Covered by MDD Annex I, ER 9.2, 12.7.1 and EN 60601-11, EN14971	Covered by GSPR 3, 14.2, 20.1
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	Covered by GSPR 3, 14.2, 20.1
1.5	RISKS DUE TO OTHER HAZARDS	No	N/A (title only)	N/A (title only)
1.5.1	Electricity supply	No	Covered in MDD Annex I ER 12 and EN 60601-1	Covered by GSPR 18, 20.4, 21
1.5.2	Static electricity	No	Covered in MDD Annex I ER 9.2 and EN 60601-1	Covered by GSPR 14.2
1.5.3	Energy supply other than electricity	No	Covered in MDD Annex I ER 12 and EN 60601-1	Covered by GSPR 18

1 In this example, 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 requirement to medical devices (Yes/No)	Rationale: ER in MDD	GSPR in MDR
1.5.4	Errors of fitting	No	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)	First part covered by EU MDR Annex I GSPR 20.5. The rest covered by EU MDR Annex I GSPR 14.1, 20.4 and 23.4 (k).
1.5.5	Extreme temperatures	No	Covered in MDD Annex I ER 9.2, 12.7.5 and EN 60601-1	Covered by GSPR 14.2, 20.6
1.5.6	Fire	No	Covered in MDD Annex I ER 9.3 and EN 60601-1	Covered by GSPR 14.3
1.5.7	Explosion	No	Covered in MDD Annex I ER 9.3 and EN 60601-1	Covered by GSPR 14.3
1.5.8	Noise	No	Covered in MDD Annex I ER 12.7.3 and EN 60601-1	Covered by GSPR 20.3
1.5.9	Vibrations	No	Covered in MDD Annex I ER 12.7.2 and EN 60601-1	Covered by GSPR 20.2
1.5.10	Radiation	No	Covered in MDD Annex I ER 11, ER 12.5 and EN 60601-1, and EN ISO 14971	Covered by GSPR 3, 16, 18.5
1.5.11	External radiation	No	Covered in MDD Annex I ER 9.2 and EN 60601-1	Covered by GSPR 14.2, 18.6
1.5.12	Laser radiation	No	Covered in MDD Annex I ER 11 and EN 60601-1	Covered by GSPR 16, 21
1.5.13	Emissions of hazardous materials and substances	No	Covered in MDD Annex I ER 7.1, 7.3, 7.5	Covered by GSPR 10.1, 10.3, 10.4
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	Covered by GSPR 14.2, 20
1.5.15	Risk of slipping, tripping or falling	No	Covered in MDD Annex I ER 12.7.1	Covered by EU MDR Annex I GSPR 20.1.
1.5.16	Lightning	No	Covered in MDD Annex I ER 9.2, 12.6 and EN 60601-1	Covered by GSPR 18.6, 18.7
1.6.	MAINTENANCE	No	N/A (title only)	N/A (title only)
1.6.1	Machinery maintenance	No	Only partially Covered in MDD Annex I ER 4, 13.6d, apply EN 60601-1 and EN14971	Covered by 23.4 (k), 14.4
1.6.2.	Access to operating positions and servicing points	No	Only partially Covered in MDD Annex I ER 4, 13.6d, apply EN 60601-1 and EN14971	Covered by 14.4, 23.4k
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	Partially covered by 18.2, 23.4k, 14.2, apply EN 60601-1 e.g. 8.11.1
1.6.4.	Operator intervention	No	Covered in MDD Annex I ER 12.7.4, 12.9, 13.6d	Covered by GSPR 18.8, 20.4, 21.3, 23.4k
1.6.5.	Cleaning of internal parts	No	Covered in MDD Annex I ER 7	Covered by GSPR 10, 11.2
1.7.	INFORMATION	No	N/A (title only)	N/A (title only)
1.7.1.	Information and warnings	No	Covered in MDD Annex I ER 11.4, 12.9, 13.1, 13.2	Covered by GSPR 21.3, 23.1, 23.2

EHSR of MD 2006/42/EC		Applicable requirement to medical devices (Yes/No)	Rationale: ER in MDD	GSPR in MDR
	on the machinery			
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	Covered by GSPR 21.3, 23.1, 23.2
1.7.1.2	Warning devices	No	Covered in MDD Annex I ER 2, 11.4, 12.3, 12.4, 13.2	Covered by GSPR 4, 18.3, 18.4, 21.3, 23.1, 23.2
1.7.2.	Warning of residual risks	No	Covered in MDD Annex I ER 2, 11.4, 12.9,13	Covered by GSPR 4,10.4.5, 23.1g,23.2, 23.4
1.7.3.	Marking of machinery	No	Covered in MDD Annex I ER 13.3	Covered by GSPR 23.1, 23.2
1.7.4.	Instructions	No	Covered in MDD Annex I ER 13	Covered by GSPR 23.1, 23.2, 23.4
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	Covered by GSPR 3, 23.1, 23.2, 23.4
1.7.4.2	Contents of the instructions	No	Covered in MDD Annex I ER 13.6, EN 60601-1 and EN 1041, EN14971	Covered by GSPR 23.1, 23.4
1.7.4.3	Sales literature	No	Covered by MDD Article 1 g) and Annex I, ER 4, 13	Covered by Art. 7, GSPR 1 & 23
2	SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR CERTAIN CATEGORIES OF MACHINERY	No	N/A (Title and explanatory text only)	N/A (Title and explanatory text only)
2.1	FOODSTUFFS MACHINERY AND MACHINERY FOR COSMETICS OR PHARMACEUTICAL PRODUCTS	No	N/A	N/A
2.2	PORTABLE HAND-HELD AND/OR HAND-GUIDED MACHINERY	No	N/A (Title only)	N/A (Title only)
2.2.1	General	No	Covered in MDD Annex I ER 9, 12	Covered by GSPR 14, 17, 18
2.2.1.1	Instructions	No	Covered in MDD Annex I ER 13.6	Covered by GSPR 23.4

EHSR of MD 2006/42/EC		Applicable requirement to medical devices (Yes/No)	Rationale: ER in MDD	GSPR in MDR
2.2.2	Portable fixing and other impact machinery	No	N/A	N/A
2.3	MACHINERY FOR WORKING WOOD AND MATERIAL WITH SIMILAR PHYSICAL CHARACTERISTICS	No	N/A	N/A
3	SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET HAZARDS DUE TO THE MOBILITY OF MACHINERY	No	Title and explanatory text only	N/A
3.1	GENERAL	No	N/A (title only)	N/A (title only)
3.1.1	Definitions	No	N/A (definition only)	N/A (definition only)
3.2	WORK POSITIONS	No	N/A (title only)	N/A (title only)
3.2.1	Driving Position	No	Covered in MDD Annex I ER 2, 4, 9	Covered by GSPR 4, 6, 14
3.2.2	Seating	No	Not relevant	N/A
3.2.3	Positions for other persons	No	Covered in MDD Annex I ER 2, 4, 9	Covered by GSPR 4, 6, 14
3.3	CONTROL SYSTEMS	No	Covered in MDD Annex I ER 2, 4, 9, 12.9 and EN 60601-11, EN ISO 14971	Covered by GSPR 3, 4, 6, 14, 21.3
3.3.1	Control devices	No	Covered in MDD Annex I ER 2, 4, 9, 12.9 and EN 60601-1, EN ISO 14971	Covered by GSPR 3, 4, 6, 14, 21.3
3.3.2	Starting/moving	No	Covered in MDD Annex I ER 2, 4, 9 and EN 60601-1, EN ISO 14971	Covered by GSPR 3, 4, 6, 14, 20, 21
3.3.3	Travelling function	No	Covered in MDD Annex I ER 2, 4, 9 and EN ISO 14971	Covered by GSPR 3, 4, 6, 14, 20, 21
3.3.4	Movement of pedestrian-controlled machinery	No	Covered in MDD Annex I ER 2, 4, 9 and EN 60601-1, EN ISO 14971	Covered by GSPR 3, 4, 6, 14, 20, 21

1 In this example, 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 requirement to medical devices (Yes/No)	Rationale: ER in MDD	GSPR in MDR
3.3.5	Control circuit failure	No	Covered in MDD Annex I ER 2, 4, 9 and EN 60601-1, EN ISO 14971	Covered by GSPR 3, 4, 6, 14, 20, 21
3.4	PROTECTION AGAINST MECHANICAL HAZARDS	No	N/A (title only)	N/A (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 ISO 14971	Covered by GSPR 3, 4, 6, 14, 20.1
3.4.2	Moving transmission parts	No	Covered in MDD Annex I ER 2, 4, 9, 12.7.1 and EN 60601-1, EN ISO 14971	Covered by GSPR 3, 4, 6, 14, 20.1
3.4.3	Roll-over and tip-over	No	Covered in MDD Annex I ER 2, 4, 9 and EN ISO 14971	Covered by GSPR 3, 4, 6, 14, 20.1
3.4.4	Falling objects	No	Covered in MDD Annex I ER 2, 4, 9 and EN ISO 14971	Covered by GSPR 3, 4, 6, 14, 20.1
3.4.5	Means of access	Yes	Only partially covered in MDD Annex I ER 2, 4, 9 and EN 60601-1, EN ISO 14971	Partially covered by GSPR 3, 4, 6, 14
3.4.6	Towing devices	No	N/A	N/A
3.4.7	Transmission of power between self-propelled machinery (or tractor) and recipient machinery	No	N/A	N/A
3.5	PROTECTION AGAINST OTHER HAZARDS	No	N/A (title only)	N/A (title only)
3.5.1	Batteries	No	Covered in MDD Annex I ER 2, 4, 7.5, 9, 12.6 and EN 60601-1, EN ISO 14971	Covered by GSPR 3, 4, 6, 10.4, 14, 18.7
3.5.2	Fire	No	Covered in MDD Annex I ER 2, 4, 9.3 and EN 60601-1, EN ISO 14971	Covered by GSPR3, 4, 6, 14.3
3.5.3	Emissions of hazardous substances	No	Covered in MDD Annex I ER 2, 4, 7.5, 9.2 and EN 60601-1, EN ISO 14971	Covered by GSPR 3, 4, 6, 10.4, 14.3
3.6	INFORMATION AND INDICATIONS	No	N/A (title only)	N/A (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 ISO 14971	Covered by GSPR 3, 4, 6, 14, 18, 23
3.6.2	Markings	Yes	Not covered in MDD; necessary only for those devices defined in MD EHSR 3.1.1	Not covered in MDR; necessary only for those devices defined in MD EHSR 3.1.1
3.6.3	Instructions	No	N/A (title only)	N/A (title only)

EHSR of MD 2006/42/EC		Applicable requirement to medical devices (Yes/No)	Rationale: ER in MDD	GSPR in MDR
3.6.3.1	Vibrations	No	Covered in MDD Annex I ER 9, 12.7.2, 13 and EN 60601-1, EN ISO 14971	Covered by GSPR 3, 14, 20.2, 23.4
3.6.3.2	Multiple uses	No	Covered in MDD Annex I ER 13.6 (c)	Covered by GSPR 23.4 k & q
4	SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET HAZARDS DUE TO LIFTING OPERATIONS	No	N/A (Title and explanatory text only)	N/A (Title and explanatory text only)
4.1.	GENERAL	No	N/A (title only)	N/A (title only)
4.1.1.	Definitions	No	N/A (definition only)	N/A (definition only)
4.1.2.	Protection against mechanical hazards	No	N/A (title only)	N/A (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 ISO 14971	Covered by GSPR 3, 7, 14, 20.1
4.1.2.2	Machinery running on guide rails and rail tracks	No	Covered by MDD Annex I, ER 2, 9, 12.7.1 and EN 60601-1, EN ISO 14971	Covered by GSPR 3, 4, 7, 14, 20.1
4.1.2.3	Mechanical strength	No	Covered by MDD Annex I, ER 4, 5, 9, 12.7.1 and EN 60601-1, EN ISO 14971	Covered by GSPR 3, 6, 10.1, 14, 20.1
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 ISO 14971	Covered by GSPR 3, 6, 14, 20.1
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 ISO 14971	Covered by GSPR 3, 6, 14, 20.1
4.1.2.6	Control of movements	No	Covered by MDD Annex I, ER 4, 9, 12.7.1 and EN 60601-1, EN ISO 14971	Covered by GSPR 3, 6, 14, 20.1
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 ISO 14971	Covered by GSPR 3, 6, 14, 20.1
4.1.2.8	Machinery serving fixed landings	No	N/A	N/A
4.1.3.	Fitness for purpose	No	Covered by MDD Annex I, ER 3 and also by EN60601-1 and EN 60601-1-6.	Covered by GSPR 1, 3, 20.1
4.2.	REQUIREMENTS FOR MACHINERY WHOSE POWER	No	N/A (title only)	N/A (title only)

EHSR of MD 2006/42/EC		Applicable requirement to medical devices (Yes/No)	Rationale: ER in MDD	GSPR in MDR
	SOURCE IS OTHER THAN MANUAL EFFORT			
4.2.1.	Control of movements	No	Covered by MDD Annex I, ER 4, 9, 12.7.1 and EN 60601-11, EN ISO 14971 and particular standards (e.g. EN60601-2-32)	Covered by GSPR 3, 6, 14, 20.1
4.2.2.	Loading control	No	N/A	N/A
4.2.3.	Installations guided by ropes	No	N/A	N/A
4.3.	INFORMATION AND MARKINGS	No	N/A (title only)	N/A (title only)
4.3.1.	Chains, ropes and webbing	No	Covered by MDD Annex I, ER 13.3, 13.5	Covered by GSPR 23.1, 23.2, 23.4k, 23.4q
4.3.2.	Lifting accessories	No	Covered by MDD Annex I, ER 13.3, 13.5	Covered by GSPR 23.1, 23.2, 23.4k, 23.4q
4.3.3.	Lifting machinery	No	Covered by MDD Annex I, ER 13.3, 13.5	Covered by GSPR 23.1, 23.2, 23.4k, 23.4q
4.4.	INSTRUCTIONS	No	N/A (title only)	N/A (title only)
4.4.1.	Lifting accessories	No	Covered by MDD Annex I, ER 13.5, 13.6	Covered by GSPR 23.4
4.4.2.	Lifting machinery	No	Covered by MDD Annex I, ER 13.5, 13.6	Covered by GSPR 23.4
5	SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY INTENDED FOR UNDERGROUND WORK	No	Whole chapter not relevant for medical devices	N/A
6	SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY PRESENTING PARTICULAR	No	N/A (Title and explanatory text only)	N/A (Title and explanatory text only)

¹ In this example, 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 requirement to medical devices (Yes/No)	Rationale: ER in MDD	GSPR in MDR
	HAZARDS DUE TO THE LIFTING OF PERSONS			
6.1.	GENERAL	No	N/A (title only)	N/A (title only)
6.1.1.	Mechanical strength	No	Covered in MDD Annex I ER 9, 12.7.1 and EN 60601-1, EN ISO 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)	Covered by GSPR 3, 6, 14, 20.1
6.1.2.	Loading control for machinery moved by power other than human strength	No	Not relevant	N/A
6.2.	CONTROL DEVICES	No	Covered by MDD Annex I ER 12.7 and EN 60601-1, EN ISO 14971, and particular standards (e.g. EN60601-2-32)	Covered by GSPR 3, 20
6.3.	RISKS TO PERSONS IN OR ON THE CARRIER	No	N/A (title only)	N/A (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	Covered by GSPR 3, 4, 14.2, 20
6.3.2.	Risk of persons falling from the carrier	No	Covered by MDD Annex I ER 2, 9.2, 12.7 and EN14971	Covered by GSPR 3, 4, 14.2, 20
6.3.3.	Risk due to objects falling on the carrier	No	Not relevant	N/A
6.4.	MACHINERY SERVING FIXED LANDINGS	No	Whole chapter not relevant	Whole chapter not relevant
6.5.	MARKINGS	No	Covered by MDD Annex I, ER 13.3	GSPR 23.2 &