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VRS-MED-201

Medical & Healthcare — AR Assessment Protocol

How the Medical & Healthcare Application Rating letter is determined — sector criteria MED-1…MED-9, contributing intrinsic criteria, letter bands, tier ceilings and class applicability, with evidence by tier and underwriting use.

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Contents

> **Foreword.** This Assessment Protocol determines the **Medical & Healthcare Application Rating (AR)** letter for a robot model in a declared clinical application class. It scores a **pool** of criteria — the nine sector criteria of Clause 6 (MED-1…MED-9, 100 points) plus the named intrinsic criteria of Clause 5, each scored once under its own standard and counted here — and expresses the earned points as a percentage of the applicable pool, which maps to a letter **C < B < A < AA < AAA (AAA best)** by the bands of VRS-GEN-006 §4. Every criterion is bounded by an evidence tier — Unverified, Verified, Certified — so the best attainable letter rises with substantiation, not assertion. This edition supersedes the re-weighted-mean model of the 0.x drafts: no weighting, no separate grade bands, no separate modifiers — the tier limits fall out of the per-criterion ceilings of Clause 6. VRS rates **above** the medical-device regulatory floor: regulatory clearance is scored evidence (MED-1), and a rating is an opinion on the robot, not on the lawfulness of any deployment. A Medical & Healthcare AR is an opinion above the compliance floor, not a certification, and nothing here implies that any real robot holds a Veyrum rating (ratings are not published). Requirements use “shall”; recommendations use “should”.

1 1 Scope

1.1 This Protocol defines, for the **Medical & Healthcare** sector Application Rating: the determination method (Clause 4); the contributing intrinsic criteria drawn into the pool (Clause 5); the nine sector criteria MED-1…MED-9 with their point ladders and tier ceilings (Clause 6); the letter bands, pool ceilings and class applicability (Clause 7); the evidence admissible at each tier (Clause 8); underwriting and credit use (Clause 9); result recording (Clause 10); and the assessor checklist (Clause 11). A worked example is at Annex A.

1.2 The AR shall be issued **per application class**. The clinical application classes are **surgical**, **rehabilitation/therapy**, **hospital logistics/service** and **care/assistive (clinical)**, per VRS-MED-001 §4. Patient-contact criteria (MED-3) apply to the contact classes (surgical, rehabilitation, care). Sector applicability, the clinical hazard taxonomy and the anchor regime are defined in VRS-MED-001 and are not restated here.

1.3 The AR shall be assessed at one of three **tiers** — Unverified, Verified, Certified. Each criterion states the maximum points reachable at each tier (Clause 6); the AR tier is the tier whose evidence bar the assessed evidence meets and shall not exceed the model’s Intrinsic Rating tier (VRS-GEN-006 §7). The underlying point aggregation and the letter bands are defined in VRS-GEN-005/006 and are not restated here.

2 2 Normative references

- **VRS-MED-001**, Medical & Healthcare — Sector Standard — applicability, clinical application classes, patient-contact hazard groups and the medical-device anchor regime.
- **VRS-GEN-005**, Intrinsic Rating — Methodology — point aggregation, tiers, cold-start parity and the company-wide fallback rule (§6).

- **VRS-GEN-006**, Application Rating — Scheme — the letter bands, the applicable-pool percentage and the tier rule.
- **VRS-GEN-009**, Robot Risk Passport and Registry Schema — the record that carries the AR result.
- **VRS-GEN-012**, Evidence Grades and Data Requirements — evidence kinds and the tier evidence bars.
- **VRS-GEN-101 … VRS-GEN-106**, IR Category Standards — the intrinsic criteria contributed under Clause 5.
- **IEC 80601-2-77:2019** (+AMD1:2023) — robotically assisted surgical equipment — surgical-class anchor.
- **IEC 80601-2-78:2019** (+AMD1:2024) — robots for rehabilitation, assessment, compensation or alleviation.
- **IEC 60601-1** family — general basic safety and essential performance of medical electrical equipment.
- **ISO 14971:2019** — application of risk management to medical devices.
- **ISO 13485:2016** — medical-device quality management systems.
- **IEC 62304:2006** — medical-device software life-cycle processes.
- **IEC 62443-3-3:2013** — system security requirements and security levels for the connected clinical system.
- **Regulation (EU) 2017/745** (Medical Device Regulation) — EU clearance pathway.
- **ISO 14224:2016** — reliability and maintenance data.
- Data twin: **VRS-MED-501** (generated from this Protocol, never hand-edited).

3 3 Terms and definitions

Terms per VRS-GEN-001 (aligned to ISO 8373:2021) and VRS-MED-001. Locally:

- **pool** — the set of criteria whose points determine the AR letter: the nine sector criteria of Clause 6 together with the contributing intrinsic criteria of Clause 5.
- **applicable pool** — the pool for a given application class after criteria not applicable to that class are removed from both the earned points and the pool range (Clause 4; VRS-GEN-006 §6).
- **contributor** — an intrinsic criterion scored once under its own IR category standard and counted again in the sector pool at the same points (Clause 5).
- **tier** — the evidence stringency at which a criterion is assessed: **Unverified** (public evidence only), **Verified** (manufacturer evidence pack examined), **Certified** (behaviour witnessed).
- **ceiling** — the maximum points a criterion awards at a given tier; points earned are capped at the ceiling of the assessed tier.
- **evidence bar** — the minimum evidence a criterion requires before any points are awarded; below it the criterion scores 0.
- **company-wide fallback** — the substitute points a criterion allows from manufacturer-wide evidence when model-specific evidence is unavailable (VRS-GEN-005 §6).
- **clinical exposure** — the count of procedures or therapy sessions and the units in clinical service, recorded for the field-record criteria (MED-8, MED-9) and for underwriting, not as a scoring input.

4 4 Method of assessment

4.1 The Medical & Healthcare AR shall be determined as a percentage of the **applicable pool** and mapped to a letter by the bands of VRS-GEN-006 §4 (Clause 7.1). The pool is the nine sector criteria of Clause 6 (MED-1…MED-9, 100 points) together with the contributing intrinsic criteria of Clause 5, each scored once under its own standard and counted here at the same points. For an application class the assessor shall add the points earned across the applicable criteria and divide by the sum of the point ranges of those same criteria; a criterion not applicable to the class (Clause 6 Applicability row; VRS-GEN-006 §6) shall be removed from both the earned points and the pool range. No weighting is applied — each criterion's point range sizes its own importance — and no separate modifiers operate on the letter: the tier limits follow from the per-criterion ceilings of Clause 6 (Clause 7.2; VRS-GEN-006 §8).

4.2 Evidence shall be attributable to the declared **clinical application class** of the assessed envelope — surgical, rehabilitation/therapy, hospital logistics/service, or care/assistive (clinical) (Clause 1.2; VRS-MED-001 §4) — and to operation under clinical governance (hygiene, electromagnetic compatibility, patient-safety reporting); the AR letter covers only the assessed classes and conditions.

4.3 Letters shall be issued **per application class** where evidence diverges materially between classes; the displayed sector letter shall be the **lowest issued class letter**. A class for which no letter can be issued shall be displayed as *not covered*, and the assessed envelope shall contract to the classes the evidence covers.

4.4 Evidence obtained outside a declared application class and its clinical setting — uncontrolled deployments, off-label use or non-clinical bench demonstrations — shall be **inadmissible** as support for that class (VRS-MED-001 Annex B.1); the letter shall not be extended to procedures never observed under clinical governance.

5 5 Contributing IR criteria

5.1 The sector pool consists of the sector criteria of Clause 6 and the following intrinsic criteria, scored once under their own standards and counted again here at the same points:

IR CRITERION	SCORED UNDER
SF-1	VRS-GEN-101 §6.1
SF-2	VRS-GEN-101 §6.2
SF-3	VRS-GEN-101 §6.3
SF-4	VRS-GEN-101 §6.4
SF-7	VRS-GEN-101 §6.7
SF-8	VRS-GEN-101 §6.8
SF-9	VRS-GEN-101 §6.9
SF-10	VRS-GEN-101 §6.10
RL-5	VRS-GEN-102 §6.5
RL-7	VRS-GEN-102 §6.7
SV-3	VRS-GEN-103 §6.3
SV-4	VRS-GEN-103 §6.4
SV-6	VRS-GEN-103 §6.6
CY-2	VRS-GEN-105 §6.2
CY-3	VRS-GEN-105 §6.3
CY-5	VRS-GEN-105 §6.5
MS-1	VRS-GEN-106 §6.1
MS-4	VRS-GEN-106 §6.4
MS-7	VRS-GEN-106 §6.7
SI-1	VRS-GEN-104 §6.1
SI-6	VRS-GEN-104 §6.5

5.2 No other intrinsic criterion contributes. Points, ceilings and applicability of a contributing criterion are those of its own standard; where a contributing criterion is not applicable to the assessed application class it is removed from the pool for that class (VRS-GEN-006 §6).

6 6 Sector criteria

6.0 Summary. Points and tier ceilings per criterion; totals reproduce by addition.

§	CRITERION	POINTS	UNVERIFIED CEILING	VERIFIED CEILING	CERTIFIED CEILING
6.1	MED-1 Regulatory clearance and standing	0–16	12	14	16
6.2	MED-2 Electrical / ME-equipment safety (IEC 60601 family)	0–10	7	8	10
6.3	MED-3 Patient-contact force / motion limits	0–14	7	10	14
6.4	MED-4 Mid-procedure failure behaviour and recovery	0–12	7	10	12
6.5	MED-5 Sterilisation / hygiene compatibility	0–8	4	7	8
6.6	MED-6 PHI, connectivity and remote access	0–12	8	9	12
6.7	MED-7 Service under validated configuration	0–8	5	7	8
6.8	MED-8 Adverse-event and malfunction record	0–12	12	12	12
6.9	MED-9 Recall and field-safety-corrective-action conduct	0–8	8	8	8
	Total	**100**	**70**	**85**	**100**

6.1 6.1 MED-1 Regulatory clearance and standing (0–16)

ROW	
What is measured	.
Ladder	16 = cleared/certified in the assessed market + notified-body CE + no open enforcement · **14 = pack-evidenced (documents), not demonstrated** · 12 = cleared in one major jurisdiction · 8 = clearance pending with published submission · 0 = none. (Public clearance databases.)
Unverified — evidence & ceiling	FDA/EUDAMED/TGA public databases. **Ceiling 12.**
Verified — evidence & ceiling	Clearance letters, technical-file summary, notified-body certificate. **Ceiling 14.**
Certified — evidence & ceiling	— (documentary). **Ceiling 16.**
Company-wide fallback	n/a
Evidence bar	Device class and intended use declared.
Applicability	surgical · rehabilitation/therapy · hospital logistics/service · care/assistive (clinical). MED-3 applies to contact classes (surgical, rehabilitation, care).

6.2 6.2 MED-2 Electrical / ME-equipment safety (IEC 60601 family) (0–10)

ROW	
What is measured	.
Ladder	10 = third-party certificate covering the system + witnessed alarm/e-stop behaviour · 8 = certificate public · **7 = publicly evidenced only (no pack, no demonstration)** · 5 = declared · 0 = not established
Unverified — evidence & ceiling	Public certificates (UL/TÜV/CB scheme). **Ceiling 7.**
Verified — evidence & ceiling	Certificates + test reports. **Ceiling 8.**
Certified — evidence & ceiling	Witnessed alarm states and emergency stop. **Ceiling 10.**
Company-wide fallback	n/a
Evidence bar	None.
Applicability	surgical · rehabilitation/therapy · hospital logistics/service · care/assistive (clinical). MED-3 applies to contact classes (surgical, rehabilitation, care).

6.3 6.3 MED-3 Patient-contact force / motion limits (0–14)

ROW	
What is measured	Contact force, speed and workspace limits appropriate to the clinical task; fault → hold-in-place.
Ladder	14 = witnessed on phantom/test rig · 10 = certified with published data · 7 = validation report · 4 = documented · 0 = not established. · 0. **Contact classes only.**
Unverified — evidence & ceiling	510(k) summary performance testing; certificates. **Ceiling 7.**
Verified — evidence & ceiling	Validation reports. **Ceiling 10.**
Certified — evidence & ceiling	Witnessed on phantom with force readings; fault injection → hold. **Ceiling 14.**
Company-wide fallback	n/a
Evidence bar	Applies to contact classes; limits declared.
Applicability	surgical · rehabilitation/therapy · hospital logistics/service · care/assistive (clinical). MED-3 applies to contact classes (surgical, rehabilitation, care).

6.4 6.4 MED-4 Mid-procedure failure behaviour and recovery (0–12)

ROW	
What is measured	On fault: controlled hold, instrument release procedure, documented recovery time; sterile-field preserved.
Ladder	12 = witnessed · **10 = pack-evidenced (documents), not demonstrated** · 8 = validated + MAUDE-consistent · **7 = publicly evidenced only (no pack, no demonstration)** · 5 = documented · 0 = not established
Unverified — evidence & ceiling	Manual; MAUDE malfunction narratives. **Ceiling 7.**
Verified — evidence & ceiling	Fault-response validation + service records. **Ceiling 10.**
Certified — evidence & ceiling	Witnessed induced fault → hold → manual recovery, timed. **Ceiling 12.**
Company-wide fallback	n/a
Evidence bar	Fault-response documented.
Applicability	surgical · rehabilitation/therapy · hospital logistics/service · care/assistive (clinical). MED-3 applies to contact classes (surgical, rehabilitation, care).

6.5 6.5 MED-5 Sterilisation / hygiene compatibility (0–8)

ROW	
What is measured	Reprocessing instructions validated; materials compatible; hygiene degradation limits stated.
Ladder	8 = validated + witnessed reprocessing steps · **7 = pack-evidenced (documents), not demonstrated** · 6 = validation documented · **4 = publicly evidenced only (no pack, no demonstration)** · 3 = instructions only · 0 = not established
Unverified — evidence & ceiling	IFU ((public)). **Ceiling 4.**
Verified — evidence & ceiling	Reprocessing validation. **Ceiling 7.**
Certified — evidence & ceiling	Witnessed reprocessing of declared components. **Ceiling 8.**
Company-wide fallback	n/a
Evidence bar	IFU exists.
Applicability	surgical · rehabilitation/therapy · hospital logistics/service · care/assistive (clinical). MED-3 applies to contact classes (surgical, rehabilitation, care).

6.6 6.6 MED-6 PHI, connectivity and remote access (0–12)

ROW	
What is measured	PHI handling, network segmentation, remote-service access controls, FDA premarket cybersecurity artefacts (SBOM, threat model).
Ladder	12 = shown + SBOM provided · 9 = documented in detail · **8 = publicly evidenced only (no pack, no demonstration)** · 5 = partial · 0 = not established
Unverified — evidence & ceiling	Public security documentation; MDS2 forms. **Ceiling 8.**
Verified — evidence & ceiling	SBOM, threat model, MDS2, access model. **Ceiling 9.**
Certified — evidence & ceiling	Console shows access controls, remote-service gating, logging. **Ceiling 12.**
Company-wide fallback	n/a
Evidence bar	Connectivity declared.
Applicability	surgical · rehabilitation/therapy · hospital logistics/service · care/assistive (clinical). MED-3 applies to contact classes (surgical, rehabilitation, care).

6.7 6.7 MED-7 Service under validated configuration (0–8)

ROW	
What is measured	Repairs within validated configurations; turnaround commitments; consumable/instrument dependency disclosed.
Ladder	8 = commitments + achieved record · **7 = pack-evidenced (documents), not demonstrated** · 6 = commitments published · **5 = publicly evidenced only (no pack, no demonstration)** · 3 = described · 0 = not established
Unverified — evidence & ceiling	Service programme descriptions. **Ceiling 5.**
Verified — evidence & ceiling	Service contract terms + repair record. **Ceiling 7.**
Certified — evidence & ceiling	— (documentary). **Ceiling 8.**
Company-wide fallback	Company-wide → 6
Evidence bar	None.
Applicability	surgical · rehabilitation/therapy · hospital logistics/service · care/assistive (clinical). MED-3 applies to contact classes (surgical, rehabilitation, care).

6.8 6.8 MED-8 Adverse-event and malfunction record (0–12)

ROW	
What is measured	MAUDE / EUDAMED reports normalised by disclosed procedure volume or install base.
Ladder	12 = low rate, all investigated · **10 = company-wide record in place of model-specific data** · 8 = moderate, investigated · 5 = elevated with corrective actions · 0 = unaddressed pattern. **Regime-full at Unverified.**
Unverified — evidence & ceiling	MAUDE, EUDAMED, disclosed volumes. **Ceiling 12.**
Verified — evidence & ceiling	Complaint-handling records + exposure. **Ceiling 12.**
Certified — evidence & ceiling	From Verified evidence. **Ceiling 12.**
Company-wide fallback	Company-wide → 10
Evidence bar	Exposure (procedures/install base) public or declared.
Applicability	surgical · rehabilitation/therapy · hospital logistics/service · care/assistive (clinical). MED-3 applies to contact classes (surgical, rehabilitation, care).

6.9 6.9 MED-9 Recall and field-safety-corrective-action conduct (0–8)

ROW	
What is measured	Recalls/FSCAs over the window: timeliness, closure, class.
Ladder	8 = none or all closed promptly · **7 = company-wide record in place of model-specific data** · 5 = closed with delay · 2 = open · 0 = Class I unaddressed. **Regime-full at Unverified.**
Unverified — evidence & ceiling	FDA recall database, FSN registers. **Ceiling 8.**
Verified — evidence & ceiling	FSCA register + closure evidence. **Ceiling 8.**
Certified — evidence & ceiling	From Verified evidence. **Ceiling 8.**
Company-wide fallback	Company-wide → 7
Evidence bar	None.
Applicability	surgical · rehabilitation/therapy · hospital logistics/service · care/assistive (clinical). MED-3 applies to contact classes (surgical, rehabilitation, care).

7 7 Letter bands, tier ceilings and class applicability

7.1 Bands (VRS-GEN-006 §4). AAA ≥ 90 % · AA ≥ 75 % · A ≥ 60 % · B ≥ 45 % · C below 45 % of the applicable pool.

7.2 Pool ceilings. Sector criteria alone: Unverified 70/100 (70 %) · Verified 85/100 (85 %) · Certified 100. With the contributing criteria of Clause 5 the pool ceilings are as recorded in VRS-MED-501; in both forms the best attainable letter is A at Unverified, AA at Verified and AAA at Certified (VRS-GEN-006 §8).

7.3 Application classes. surgical · rehabilitation/therapy · hospital logistics/service · care/assistive (clinical). MED-3 applies to contact classes (surgical, rehabilitation, care)… A criterion whose Applicability row excludes the assessed class is removed from both the numerator and the denominator; the letter is issued per class and the displayed letter is the lowest (Clause 4).

7.4 No modifiers, caps or gates operate on the letter other than the ceilings of Clause 6 and the tier rule of VRS-GEN-006 §7.

8 8 Evidence by tier

8.1 Unverified. The assessor works only from evidence obtainable without the manufacturer’s cooperation: public clearance databases (FDA, EUDAMED, TGA), public certificates (UL/TÜV/CB scheme),

510(k) summary performance testing, instructions-for-use, public security documentation and MDS2 forms, and — for the field-record criteria (MED-8, MED-9) — the MAUDE and EUDAMED adverse-event databases, the FDA recall database and field-safety-notice registers. Each criterion's Unverified ceiling (Clause 6) is the most an honest reading of such evidence shall earn; the AR tier is **Unverified**.

8.2 Verified. The assessor additionally examines a manufacturer evidence pack and shall accept, by mapping, the conformity artefacts the manufacturer already holds: the IEC 80601-2-77:2019 (+AMD1:2023) or IEC 80601-2-78:2019 (+AMD1:2024) essential-performance file with the IEC 60601-1 family general-safety evidence and the ISO 14971:2019 risk-management file (MED-1…MED-3); the fault-response validation and service records (MED-4); the reprocessing validation (MED-5); the IEC 62443-3-3:2013 security-level statement, IEC 62304:2006 software life-cycle documentation, SBOM, threat model and PHI data-flow declaration (MED-6); the ISO 13485:2016 service and validated-configuration change-control records (MED-7); and the complaint-handling and field-safety-corrective-action / CAPA records (MED-8, MED-9). Adoption is therefore a mapping, not new testing. Verified ceilings apply only to criteria whose pack items are present and examined; the AR tier is **Verified**.

8.3 Certified. The assessor witnesses the declared behaviour on the robot and its own console: the alarm states and emergency stop (MED-2); the patient-contact force and motion limits on a phantom with fault injection to hold (MED-3); an induced mid-procedure fault with controlled hold and timed manual recovery (MED-4); the reprocessing of declared components (MED-5); and the access controls, remote-service gating and logging on the console (MED-6). The documentary criteria (MED-1, MED-7, MED-8, MED-9) carry their Certified points from the Verified evidence. The AR tier is **Certified**.

8.4 Evidence bar. Each criterion states an **evidence bar** (Clause 6). Where the bar is not met the criterion shall score **0** — no evidence is 0 points, never a removal from the pool. A manufacturer self-declaration shall not earn points above the rung its independent corroboration supports.

8.5 Adverse-event registry search. For MED-8 a recorded search of the adverse-event registries (MAUDE-class and EUDAMED), with its coverage and any null result stated, shall be made before the criterion earns points; an unrecorded search shall not earn them.

8.6 Company-wide fallback. Where a criterion offers a company-wide fallback (MED-7, MED-8, MED-9) and model-specific evidence is unavailable, manufacturer-wide records shall earn the stated fallback points (VRS-GEN-005 §6); the substitution shall be recorded per Clause 10.

8.7 AR tier. The AR tier is the lowest tier among the criteria that determined the letter, and shall not exceed the model's Intrinsic Rating tier (VRS-GEN-006 §7).

9 9 Underwriting and credit use

9.1 The letter is an opinion above the compliance floor, not a certification, and shall not be published or imply that any real robot holds a Veyrum rating. A rating is an opinion on the robot, not on the lawfulness of any deployment: absence of a regulatory clearance scores 0 on MED-1 (Clause 6.1) and lowers the letter, but does not by itself withhold a rating.

9.2 The per-class letters and the recorded clinical setting are the underwriting hooks: the letter informs rate relativity, and the covered classes inform coverage scope, so that operation outside the assessed envelope is an exclusion or a condition rather than an implied covered risk. Three loss drivers shall be

surfaced separately so an underwriter can weight them independently of the letter: the **patient-contact bodily-injury severity** driver (MED-3, the sector-defining third-party injury risk); the **correlated cyber / PHI accumulation** driver (MED-6, recording whether the connected clinical system holds an IEC 62443-3-3:2013 security-level statement, so that a per-fleet or per-network accumulation limit can be set for PHI exposure or remote access across a hospital fleet); and the **recall / field-safety-corrective- action** driver (MED-9, because a single defective cleared model across many hospitals is one loss event with many claims). The MED-7 service posture informs the operator's coverage conditions.

9.3 For credit, the reliability, serviceability and support drivers shall be readable from the recorded per-criterion points to inform LTV, residual curves and end-of-support assumptions: MED-7 and the intrinsic reliability, serviceability and support criteria drawn into the pool (Clause 5) inform the obsolescence assumption. A withdrawn or narrowed clearance shall be treated as a residual-value cliff: a model whose cleared indications lapse has no lawful clinical market and shall be assumed to depreciate to salvage unless a retained clearance in another major market is evidenced.

10 10 Result recording

The rating record shall carry, per VRS-GEN-009: the displayed sector letter and the per-class letters with the class each was issued for; the **per-criterion points** earned across the sector criteria (Clause 6) and the contributing intrinsic criteria (Clause 5); the **not-applicable set** removed for each class and the resulting applicable-pool range; the contributing intrinsic criteria used; the AR **tier**; the **edition** (VRS 2026); the VRS-MED-501 data-twin version; the regulatory pathway and clearance identifiers relied on (VRS-MED-001 Annex B.4); the adverse-event registry search record including any null result (VRS-MED-001 Annex B.2); the recorded clinical exposure (procedures or therapy sessions and units in clinical service); and the connected-system PHI / remote-access posture with its IEC 62443-3-3:2013 security level (MED-6). Recording flows to the Passport per VRS-GEN-009; no patient-identifiable information shall be stored (VRS-GEN-012 §5.2).

11 11 Assessor checklist

An assessor with this Protocol and the evidence shall reach the same result by executing the following in order; no step admits an unrecorded judgement call, and any deviation shall be recorded with its basis:

- [ ] Application class(es) confirmed (surgical / rehabilitation/therapy / hospital logistics/service / care/assistive) (Clause 1.2; VRS-MED-001 §4).
- [ ] Assessment tier fixed (Clause 8); the not-applicable set recorded per class and the applicable-pool range computed (Clause 4).
- [ ] Contributing intrinsic criteria drawn from their source standards at their own points and tiers (Clause 5).
- [ ] **MED-1** regulatory clearance and standing scored; device class and intended use declared (evidence bar); absence scores 0, not a withheld rating (Clause 9.1).
- [ ] **MED-2** electrical / ME-equipment safety scored.
- [ ] **MED-3** patient-contact force / motion limits scored (contact classes only: surgical, rehabilitation, care).
- [ ] **MED-4** mid-procedure failure behaviour and recovery scored.

- [ ] **MED-5** sterilisation / hygiene compatibility scored.
- [ ] **MED-6** PHI, connectivity and remote access scored; connectivity declared (evidence bar).
- [ ] **MED-7** service under validated configuration scored; company-wide fallback recorded if used.
- [ ] **MED-8** adverse-event and malfunction record scored; registry search recorded per Clause 8.5; company-wide fallback recorded if used.
- [ ] **MED-9** recall and field-safety-corrective-action conduct scored; company-wide fallback recorded if used.
- [ ] Points added and divided by the applicable-pool range; letter read from the bands (Clause 7.1).
- [ ] Letters issued per class; the lowest displayed (Clause 4.3); each award held at its assessed-tier ceiling (Clause 6).
- [ ] Result recorded to the passport: per-criterion points, not-applicable set, contributors, tier, edition, twin version (Clause 10).

12 Annex A (informative) — Worked example

> **FICTIONAL EXAMPLE — not a real product; illustrates mechanics only.**

A fictional robotically assisted surgical system, model code `MED-RS-01`, is assessed for the **surgical** application class at the **Verified** tier: a manufacturer evidence pack is examined and no behaviour is witnessed. All nine sector criteria apply to the surgical class (a contact class), and the twenty-one contributing intrinsic criteria of Clause 5 are drawn from their source standards at their own Verified points.

Sector criteria (Verified tier).

§	CRITERION	VERIFIED CEILING	POINTS EARNED
6.1	MED-1	14	14
6.2	MED-2	8	8
6.3	MED-3	10	10
6.4	MED-4	10	10
6.5	MED-5	7	7
6.6	MED-6	9	9
6.7	MED-7	7	7
6.8	MED-8	12	10 (company-wide record)
6.9	MED-9	8	8
	Sector subtotal	**85**	**83**

Contributing intrinsic criteria (Verified tier). Drawn at their own points, the twenty-one criteria of Clause 5 have a combined range of **171 points** and a Verified ceiling of **145**; this model earns **138** of them (each at its Verified ceiling except the primary protective function SF-4, earning 9 of 11; the field safety record SF-9, earning 9 of 12; and the restoration-time criterion SV-4, earning 6 of 8).

Letter. The applicable pool for the surgical class is the sector range 100 plus the contributor range 171 = **271 points**. Points earned = 83 (sector) + 138 (contributors) = **221**. As a percentage of the pool, 221 ÷ 271 = **81.5 %**, which falls in the **AA** band (≥ 75 %, below AAA's 90 %). The result is **Medical & Healthcare AR: AA (VRS 2026) — Verified**.

Tier ceiling by construction. At the Verified tier the pool's own ceiling is (85 + 145) ÷ 271 = 230 ÷ 271 = 84.9 %, so AA is the best letter attainable without a witnessed demonstration (Clause 7.2); AAA would require Certified-tier evidence. No separate modifier is applied — the ceiling does the work.

Loss-driver read. MED-3 feeds the patient-contact bodily-injury severity driver; MED-6 records the connected-system IEC 62443-3-3:2013 security level for the correlated PHI / cyber accumulation limit; MED-9 records recall / field-safety-corrective-action conduct for the correlated device-fleet driver (Clause 9.2).

Clearance variant. Had `MED-RS-01` held no evidenced regulatory clearance for the surgical class, MED-1 would score **0** rather than 14, and the letter would fall out of the reduced total — the model is still rated (there is no clearance gate), and the missing clearance is surfaced to the underwriter as a residual-value cliff (Clause 9.3). Numbers illustrate mechanics only.

13 Bibliography

The full MED anchor regime is verified in VRS-MED-001; the following are the specific anchors this Protocol's criteria and evidence tiers (Clauses 6 and 8) rest on, dated at point of use:

- IEC 80601-2-77:2019 (edition 1.0) + AMD1:2023 — Medical electrical equipment — Part 2-77: basic safety and essential performance of robotically assisted surgical equipment (RASE/RASS); FDA recognized-consensus standard (iso.org 68473 / 83340; webstore.iec.ch/publication/89957).
- IEC 80601-2-78:2019 (edition 1.0) + AMD1:2024 — Medical electrical equipment — Part 2-78: medical robots for rehabilitation, assessment, compensation or alleviation; IEC/DIS 80601-2-78 replacement in progress (iso.org 68474 / 83341 / 90453; webstore.iec.ch/publication/93014).
- ISO 14971:2019 (edition 3) — Medical devices — Application of risk management to medical devices (iso.org 72704).
- IEC 62304:2006 (edition 1) — Medical device software — Software life-cycle processes (iso.org 38421).
- ISO 13485:2016 (edition 3) — Medical devices — Quality management systems — Requirements for regulatory purposes (iso.org 59752).
- Regulation (EU) 2017/745 (Medical Device Regulation), in force 25 May 2017, applicable 26 May 2021 — eur-lex.europa.eu CELEX 32017R0745.
- ISO 14224:2016 — Collection and exchange of reliability and maintenance data for equipment (iso.org 64076).
- IEC 62443-3-3:2013 — System security requirements and security levels SL 1–4 (webstore.iec.ch/publication/7033).
- ISO 8373:2021 — Robotics — Vocabulary (iso.org/standard/75539.html) — robot-term basis.
- VRS-MED-501 — machine-readable data twin of this Protocol (Clause 5/6/7 values).

14 Change history

DATE	VERSION	STATUS	CHANGE	AUTHORITY
2026-09-16	1.0.0	Draft	VRS 2026 rewrite: replaced the re-weighted-mean scoring (Clauses 4–8) with a point-summed pool — nine sector criteria MED-1…MED-9 (100 points; Clause 6) plus the named contributing intrinsic criteria (Clause 5), expressed as a percentage of the applicable pool and mapped to a letter by VRS-GEN-006 §4; added per-criterion tier ceilings, the letter-band/pool-ceiling/class-applicability clause (Clause 7), evidence-by-tier (Clause 8), a regenerated Verified-tier worked example (Annex A) and a per-criterion checklist (Clause 11); added the clinical application-class list (surgical / rehabilitation-therapy / hospital logistics-service / care-assistive); re-anchored the former §7 modifiers into criterion rungs and evidence bars (7.1 no-clearance rule → MED-1 = 0, still rated per §9.1; 7.2 anchor-conformity cap → MED-2; 7.3 registry-search-mandatory → MED-8 evidence bar and Clause 8.5); retired confidence bands, provisional flags, renormalisation, weighted-mean, assessed-unrated and stage-`prior` markers; dropped GEN-201/GEN-202 references; VRS-MED-501 data twin regenerated by the dispatcher from Clauses 5–7; see GEN-005 §6.	VRS 2026 rewrite Stage 4
2026-09-14	0.3.0ε1	Draft	COHERENCE: corrected stale exposure cross-reference in §8.1 — “VRS-GEN-012 §4.1” (evidence-grade scale) → §7 (Exposure and denominators). Editorial only; no requirement, weight, band, or constant changed; twin VRS-MED-501 payload value unchanged (citation mirrored).	Curator Run #183; charter COHERENCE
2026-09-13	0.3.0	Draft	ACTUARIAL: closed the C4 correlated-cyber accumulation gap — added the **shared-vector accumulation basis** (units and clinical sites sharing the fleet-update / remote-access / PHI data plane) to §8.1 so the accumulation §9.2 surfaces can be sized, reusing the §8.2 C4 evidence (IEC 62443-3-3:2013 SL statement + PHI data-flow declaration), no new testing; recorded the C4 accumulation attribute in §10 and added it to assessor checklist step 5; aligned §9.2 to a per-fleet/per-network accumulation cap. Fixes an asymmetry vs C6 (units-in-clinical-service) and the IND-201 precedent. No weight, band, or sufficiency-constant value changed; no loss statistic invented. Twin VRS-MED-501 regenerated to 0.3.0. Net +283 words.	Curator Run #92; charter ACTUARIAL

DATE	VERSION	STATUS	CHANGE	AUTHORITY
2026-09-12	0.2.0	Draft	DEEPEN: added the three MED exposure denominators (clinical procedures / op-hours / units-in-clinical-service §8.1), evidence-lane conformity-artefact reuse (§8.2, dated anchors), loss-driver mapping (§5.2), underwriting/credit use (§9), passport recording (§10, GEN-009), admissibility & grading gates (§4.3/§8.4/§8.5), assessor checklist (§11), worked example producing a letter (Annex A), dated Bibliography; retired bare pending markers → stage `prior` labels (VRS-GEN-202). No weight, band or sufficiency-constant value changed. Twin VRS-MED-501 regenerated to 0.2.0. Net +~1,600 words.	Curator Run #51; charter DEEPEN
2026-09-05	0.1.0	Draft	Initial draft — MED rubric; no-clearance-no-letter + registry-search-mandatory modifiers	CEO goal 2026-09-05

About Veyrum Research Institute

Veyrum Research Institute is the research arm of Veyrum — the independent intelligence and trust layer for the robotics industry (research, ratings and registry, advisory, data, and specialist insurance & finance introductions).

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