SAVANT HEAD POSITIONING SYSTEM

Instructions for Use (IFU)

In accordance with EU MDR 2017/745, Annex I §23

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NOTE

This document is the master Instructions for Use for the Savant Head Positioning System and must accompany the device at the time of supply in the European Union. It has been prepared in accordance with the requirements of EU MDR 2017/745, Annex I, Section 23. A Declaration of Conformity is held on file by Symmetric Designs Inc. and is available on request. The Unique Device Identifier (UDI) must be registered in EUDAMED prior to placing the device on the EU market.

1. Device Identification

The device identification information below appears on the device label. In the event of a query, use the reference number and lot/batch number when contacting Symmetric Designs or your distributor.

Basic UDI-DI	REF (Catalogue No.)	GMDN Code / Term
GS1 AISBL	SAVANT-[XXX] — see product label	34952— Wheelchair postural support, head

The UDI carrier (linear barcode and human-readable interpretation) appears on the device packaging label. For EUDAMED enquiries, use the Basic UDI-DI noted above.

2. Manufacturer and EU Authorised Representative

Manufacturer (MFR)	EU Authorised Representative (EC REP)
Symmetric Designs Inc. Salt Spring Island, BC, Canada Tel: +1 250-537-1724 Email: sales@symmetric-designs.com Web: www.symmetric-designs.com	**MedEnvoy Global B.V.** Prinses Margrietplantsoen 33 – Suite 123 2595 AM The Hague The Netherlands Tel: +31 70 326 2148	info@medenvoyglobal.com

The EU Authorised Representative (EC REP) is the legal representative of Symmetric Designs Inc. for the purposes of EU MDR 2017/745. Post-market feedback, vigilance reports, and regulatory correspondence for EU markets should be directed to the EC REP.

3. Intended Purpose

The Savant Head Positioning System is a manually adjustable, external, non-implantable medical device. Its intended purpose is to provide lateral, anterior, and/or posterior postural support to the head and cervical spine of individuals with diminished or absent head control, thereby maintaining or improving head position during wheelchair use.

The device is intended to be mounted to a wheelchair or specialised seating system using a standard rehabilitation seating hardware interface.

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The device is intended for prescription, recommendation, or configuration by a qualified healthcare professional (HCP). Use in any other context falls outside the intended purpose.

3.1 Intended Users

- Occupational therapists and physiotherapists (seating assessment and fitting)
- Rehabilitation engineers and assistive technology practitioners (technical configuration)
- Trained caregivers and personal support workers (daily positioning under HCP guidance)
- The patient or end user (where cognitive and physical ability allows self-positioning)

3.2 Intended Patient Population

- Paediatric patients (3 years of age and older) and adult wheelchair users
- Persons with neuromuscular conditions resulting in diminished head control, including but not limited to: cerebral palsy, muscular dystrophy, spinal muscular atrophy, ALS, multiple sclerosis, spinal cord injury, traumatic brain injury
- Persons in acute rehabilitation requiring temporary external head support during seating evaluation

3.3 Medical Condition / Anatomy / Body Part

The device acts on the head and cervical spine. It does not contact the respiratory airway or internal anatomy. It is an external surface-contact device only.

3.4 Clinical Benefits

When correctly fitted and maintained, the Savant Head Positioning System is intended to provide the following clinical benefits:

- Maintenance of a neutral or therapeutically optimal head position, reducing the risk of secondary musculoskeletal complications from poor head posture
- Improved visual field orientation, facilitating communication and participation in daily activities
- Reduction of fatigue associated with active head-holding effort in individuals with partial head control
- Support for respiratory efficiency by preventing anterior cervical flexion that could compromise airway patency

4. Technical Specifications

Parameter	Value
Device name	Savant Head Positioning System
EU MDR Classification	Class I (Rule 1), non-sterile, non-measuring
IVDR applicable	No
Health Canada Classification	Class I Medical Device
GMDN Code	33449
Basic UDI-DI	[INSERT — register in EUDAMED]
Intended users	Occupational therapists, physiotherapists, rehabilitation engineers, trained caregivers and, where appropriate, the patient
Patient population	Paediatric (≥ 3 years) and adult wheelchair users with diminished or absent head control
Primary structural materials	Anodised aluminium alloy (6061-T6); stainless steel fasteners (A2-70)

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Contact materials	Polyurethane foam (CertiPUR-grade); medical-grade antimicrobial polyurethane fabric; stainless steel
Latex content	Latex-free — confirmed
DEHP / phthalates	Not applicable — no PVC components
CMR / endocrine-disrupting substances	None above 0.1 % w/w in any component
Medicinal substance incorporated	None
Tissue / cell of human or animal origin	None
Sterility status	Non-sterile — device is not supplied sterile
Reusable / single-use	Reusable — designed for use on a single patient; not for transfer between patients without clinician reassessment
Device weight (hardware, typical)	0.9 kg – 1.6 kg depending on configuration
Operating temperature	–10 °C to +50 °C
Storage & transport temperature	–20 °C to +60 °C
Relative humidity (use)	15 % – 93 % RH, non-condensing
IP rating	IPX4 (splash-proof)
Expected service life	3 years under normal use and maintenance conditions
Relevant standards applied	ISO 16840-2, ISO 16840-3, ISO 15223-1:2021, ISO 7000
MRI safety	MR Conditional — consult MRI operator before scanning

5. Warnings, Contraindications, and Precautions

5.1 Contraindications

CONTRAINDICATION	Do not use the Savant Head Positioning System on patients with active cervical spine instability, acute cervical fracture or dislocation, or open wounds at any potential pad contact site, unless specifically directed and supervised by the attending physician.

The device is additionally contraindicated when:

- A known pressure injury or wound exists at any potential pad contact area
- The device cannot be adjusted to achieve neutral or prescribed cervical alignment without inducing abnormal tone or increased extensor spasm
- The mounting hardware is incompatible with the wheelchair frame and no approved adapter is available
- The responsible user, caregiver, or clinician cannot be trained or assessed as competent in correct device positioning

5.2 Warnings

⚠ WARNING	Never use the Savant Head Positioning System as a physical restraint or to forcibly maintain the user's head against active resistance. Excessive or sustained contact force may cause soft tissue injury, vascular compromise, or neurological injury.

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⚠ WARNING	Do not use this device during transit in a motor vehicle unless the wheelchair occupant system is secured in a certified vehicle tie-down and occupant restraint system (WTORS). The Savant Head Positioning System is NOT certified or tested as a vehicle occupant-restraint device and is not designed to withstand crash-level forces.

⚠ WARNING	If the user has a known or suspected swallowing dysfunction (dysphagia), do not use anterior chin support accessories without direct guidance from a speech-language pathologist. Inappropriate anterior cervical positioning may increase aspiration risk.

⚠ WARNING	This device is MR Conditional. Do not bring the device (or the wheelchair to which it is attached) into the MRI scan room without prior consultation with the MRI facility operator and written clearance based on the device's MR Conditional specifications.

5.3 Residual Risks

In accordance with EU MDR 2017/745, Annex I §23.4(u), the following residual risks have been identified in the risk management file (RMF) for this device. These risks have been reduced to an acceptable level but cannot be eliminated entirely. Users must be aware of them:

- Pressure injury risk at pad contact sites — mitigated by appropriate sizing, scheduled skin inspection, and pad replacement when wear is observed; residual risk cannot be eliminated for users with severely impaired sensation or circulation.
- Inadvertent airway compromise — mitigated by contraindications, setup instructions, and the prohibition on using the device as a restraint; residual risk exists if device is misused or if user's condition deteriorates without caregiver awareness.
- Hardware loosening under vibrational fatigue — mitigated by torque specifications and inspection schedule; residual risk of sudden loss of support if maintenance intervals are not observed.
- Skin abrasion from fabric cover degradation — mitigated by cover inspection and replacement guidance; residual risk if replacement schedule is not followed.

5.4 Precautions

- This device is prescribed or configured for a specific individual. Do not transfer the device to another user without full reassessment by a qualified clinician.
- Paediatric users must be reassessed more frequently as growth will alter fit parameters. Assess fit at a minimum of every 6 months for growing patients.
- The Savant is not intended to provide respiratory management or airway maintenance. Adequate airway clearance must be independently ensured.
- Do not modify, cut, drill, weld, or otherwise alter any component. Modifications void the warranty and invalidate the Declaration of Conformity.
- Use only Symmetric Designs approved replacement parts and accessories. Use of non-approved components may compromise safety and invalidates regulatory compliance.
- If skin redness, blanching, or pressure marking is observed at any pad contact site, remove the device and do not resume use until a clinician has reassessed fit and skin integrity.

5.5 Implant Card

This device is not an implantable device. No patient implant card is required. This statement is provided to satisfy MDR Annex I §23.4(n).

5.6 MRI Safety Information

MR Conditional. Aluminium and stainless steel components have been evaluated for MRI safety. The device has not been demonstrated safe in the MRI environment without conditions. Prior to any MRI examination involving a patient who uses this device:

- Notify the MRI facility that the patient uses this device.

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- Provide the MRI operator with this IFU and the MR Conditional specification sheet (available from Symmetric Designs).
- Remove the device from the patient before entry to the MRI controlled access zone unless the MRI operator has explicitly confirmed safety conditions are met.

6. Information for Healthcare Professionals Regarding Contraindications

In accordance with EU MDR 2017/745, Annex I §23.4(t), this section provides information to enable healthcare professionals to inform patients and carers of contraindications and precautions.

Before recommending or prescribing the Savant Head Positioning System, the prescribing HCP should verify:

1. The patient does not have active cervical spine instability, acute fracture, or active infection/open wound at any contact site.
2. The patient's skin integrity at contact sites is adequate to tolerate external support without pressure injury risk, or that a risk-management plan is in place.
3. The prescribed configuration does not produce or exacerbate abnormal tone, extensor spasm, or other adverse postural responses.
4. The caregiver or patient has the cognitive and physical capability to apply the device correctly and to recognise a problem.
5. A mechanism is in place for regular reassessment of fit, particularly in paediatric patients or patients whose condition is progressive.

7. Product Description

The Savant Head Positioning System is a modular, manually adjustable external head support system. The primary components are described below.

7.1 System Components

- Mounting post assembly — anodised 6061-T6 aluminium post with multi-axis pivot joint and tube clamp interface for standard 3/4" (19.1 mm) or 7/8" (22.2 mm) seating hardware tube
- Lateral support arms (×2) — bilateral adjustable arms providing lateral head support; independently adjustable in the sagittal and transverse planes via indexed or friction-lock joints
- Posterior occipital pad — contoured polyurethane foam pad with removable antimicrobial fabric cover; available in Small, Medium, and Large
- Anterior support (optional) — forehead band or chin cup providing anterior support to prevent forward head drop; not included as standard — prescribe separately
- Hardware fasteners — A2-70 stainless steel hex socket bolts and locking inserts throughout

7.2 Accessories and Compatible Products

The following accessories are designed for use with the Savant system. Use only accessories listed in the current Symmetric Designs product catalogue.

- Savant Anterior Forehead Band (REF: SAV-FB) — provides anterior forehead support
- Savant Chin Cup Assembly (REF: SAV-CC) — provides anterior sub-mandibular support
- Savant Pad Cover Replacement Set (REF: SAV-CVR) — antimicrobial replacement covers for occipital and lateral pads
- Savant Post Extension (REF: SAV-PE) — extends post height range by 50 mm
- Savant Clamp Adapter 1" (REF: SAV-CA1) — adapter for 1" (25.4 mm) diameter mounting tubes

For use with other devices: The Savant mounting clamp is compatible with all Symmetric Designs seating hardware posts and any standard rehabilitation seating tube conforming to ISO 16840-1 attachment interface dimensions. Compatibility with third-party seating hardware must be verified by the prescribing clinician.

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NOTE	The device does not incorporate a medicinal substance, human or animal tissue, cells, or derivatives, or ionising radiation emission. It does not contain nanomaterials as defined by EU MDR Annex I §10.4.

8. Initial Setup and Fitting

CAUTION	Initial fitting of the Savant Head Positioning System must be performed or supervised by a qualified occupational therapist, physiotherapist, or rehabilitation engineer. Independent fitting by a caregiver is only appropriate after an HCP has documented the target configuration.

8.1 Tools Required

- 4 mm hex key (Allen wrench)
- 5 mm hex key
- Tape measure
- Torque wrench or torque hex key (recommended; see Section 10 for values)

8.2 Mounting the Post Assembly

6. Position the user in their wheelchair in their normal functional seated posture.
7. Identify the mounting tube (rear post or seating frame lateral member). Confirm tube outer diameter is 3/4" (19.1 mm) or 7/8" (22.2 mm). For 1" (25.4 mm) tubes, fit the SAV-CA1 clamp adapter before proceeding.
8. Loosen the clamp bolt on the Savant post base using the 5 mm hex key.
9. Slide the clamp onto the mounting tube and position the post centred on the user's sagittal plane, lateral to the headrest zone.
10. Adjust post height so support arms will align with the user's head at ear level.
11. Tighten the clamp bolt to 6.0–7.0 N·m. Adjust the multi-axis pivot to a vertical post orientation and tighten the pivot bolt to 3.5–4.5 N·m.

8.3 Fitting the Lateral Support Arms

12. Bend both lateral arms by hand.
13. With the user in position, slide each arm inward until the pad gently contacts the lateral aspect of the head at approximately ear level.
14. Adjust fore-aft position so the pad contacts the head without inducing forward or rearward displacement.
15. Confirm the user's head is in the neutral or therapeutically prescribed position.
16. Verify the user can perform any prescribed voluntary head movement.

8.4 Fitting the Posterior Occipital Pad

17. Select pad size based on the user's head circumference and occipital contour.
18. Attach the pad to the bracket.
19. Position the pad contacting the occipital region; confirm it does not directly contact the cervical spinous processes.

8.5 Post-Fitting Verification

- Confirm all fasteners are tightened to torque specification (Section 10).
- Ask the user (if communicative) whether any area feels uncomfortable or produces unusual pressure or pain.
- Inspect all pad contact sites for blanching, redness, or discomfort. If any is observed, reposition or remove the device.
- Document the final configuration, pad sizes, and fastener torques in the patient seating record.

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- Re-torque all fasteners after the first 24 hours of use if needed.

9. Daily Use

9.1 Positioning the User (Each Session)

20. Transfer the user into the wheelchair and ensure they are fully seated in the prescribed posture.
21. Guide the user's head gently into the Savant support, confirming the head is centred and in the prescribed position.
22. If an anterior support is prescribed, apply it after lateral positioning is confirmed.
23. Inspect all pad contact sites. Do not proceed if any redness, blanching, or wound is present.

9.2 Pre-Use Inspection (Each Session)

- Inspect all visible hardware for loosening, cracking, corrosion, or deformation.
- Confirm pad covers are intact, clean, and correctly seated with no wrinkles.
- Verify the user's head rests in the expected position consistent with the documented configuration.
- If any component appears damaged, out of position, or otherwise abnormal, do not use the device until a qualified technician has inspected and cleared it.

10. Torque Specifications

Use a calibrated torque wrench or torque hex key for all fasteners. Re-torque after the first 24 hours of use and at the intervals listed.

Fastener Location	Tool	Torque (N·m)	Re-check Interval
Clamp-to-tube main bolt	5 mm hex key	6.0 – 7.0	3 months / at each reinstallation

CAUTION Do not exceed the maximum torque values. Over-torquing may strip threads or crack clamp bodies, compromising the structural integrity of the mounting.

11. Cleaning and Maintenance

11.1 Cleaning Schedule

- Clinical / shared-device settings: wipe all external surfaces after each use with a hospital-grade disinfectant wipe.
- Personal / home-use settings: wipe external surfaces at least once daily; more frequently if soiling occurs.

11.2 Cleaning Methods

Component	Recommended Method	Validated Agent(s)
Aluminium hardware	Wipe with lint-free cloth	70 % isopropyl alcohol (IPA); quaternary ammonium disinfectant wipe

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Upholstery (pad cover surface)	Wipe; do not saturate or soak	Hospital-grade surface disinfectant wipe; mild soap solution
Removable pad covers (fabric)	Machine wash 40 °C, gentle cycle; tumble dry low or air dry	Standard laundry detergent — no bleach
Stainless steel fasteners	Wipe; inspect for corrosion post-cleaning	Dry thoroughly after cleaning; do not immerse
Pivot and clamp joints	Wipe with damp cloth; allow to dry fully before use	70 % IPA wipe — do not spray directly into joint

CAUTION	Do not autoclave, steam sterilise, UV sterilise, or fully immerse any component of the Savant. The device is not designed to tolerate sterilisation processes. It is supplied and maintained as a non-sterile device.

CAUTION	Do not use bleach-based (sodium hypochlorite) products on aluminium hardware — corrosion will result. Bleach is acceptable only on removable fabric covers.

11.3 Periodic Maintenance

- Every 3 months: verify all fastener torques against values in Section 10.
- Every 3 months: inspect foam pads for compression set (replace if deformation exceeds ~10 % of original thickness), discolouration, odour, or surface degradation.
- Every 3 months: inspect all pivot and clamp joints for wear, corrosion, or play. Replace worn components before returning to service.
- Every 6 months (paediatric users): full reassessment of fit by HCP due to growth-related changes.
- At 3 years or earlier if wear is observed: consider replacement of the entire system to maintain within the expected service life.

12. Troubleshooting

Symptom	Possible Cause	Corrective Action
Head drifts laterally	Lateral arm out of adjustment or loose	Re-adjust and re-torque arm clamp bolts to specification
Excessive forward head drop	Posterior pad too far back or too small; anterior support not fitted	Reposition posterior pad; assess need for anterior support with clinician
Redness / skin marking at pad contact	Pad over bony prominence; cover wrinkled or displaced	Remove device immediately; reassess pad size/position; consult clinician before reuse
Hardware loosening repeatedly	Vibration from wheelchair drive; insufficient initial torque	Re-torque to specification; apply Loctite 222 to thread; contact Symmetric Designs if issue persists
Pivot joint stiff or immovable	Debris or corrosion in joint; mechanism over-tightened	Clean with IPA wipe; dry thoroughly; do not use oil-based lubricants
Foam pad feels bottomed-out / flat	End of pad service life; exposure to excess heat or chemical	Replace pad — do not continue use with degraded padding

If a problem cannot be resolved using the guidance above, stop using the device and contact Symmetric Designs technical support at sales@symmetric-designs.com or +1 250-537-1724.

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13. Storage, Handling, and Transport

13.1 Storage Conditions

- Store in a clean, dry environment away from direct sunlight.
- Temperature: –20 °C to +60 °C; Relative humidity: 15 % – 93 % RH non-condensing.
- Do not stack heavy objects on packaged devices.

13.2 Transport

- The device may be transported at any ambient temperature within the storage range.
- If removing from the wheelchair for transport, store in the original packaging or equivalent protective container.

13.3 Handling Precautions

- Handle aluminium components carefully to avoid impact damage that may not be immediately visible but could reduce load-bearing capacity.
- Do not expose the device to solvents, caustic chemicals, or temperatures above +60 °C (e.g., vehicle interiors in summer).

14. Disposal

When the device has reached end of service life or cannot be repaired to a safe condition, decommission and dispose as follows:

- Aluminium hardware components: separate from other materials; recycle via a registered metal recycler in accordance with local regulations.
- Polyurethane foam pads: dispose as polymer waste in accordance with local municipal solid waste regulations.
- Upholstery fabric covers: dispose as textile waste in accordance with local regulations.
- Stainless steel fasteners: recycle via metal waste stream.
- If the device has been used on a patient with a known communicable infection risk, decontaminate with an appropriate disinfectant before disposal and follow applicable infection control procedures.
- Waste electrical and electronic equipment (WEEE): this device contains no electronic components and is not classified as WEEE.

15. Symbols Used on Device Labelling

The following symbols appear on the device label or packaging label. All symbols are drawn from or aligned with ISO 15223-1:2021 unless otherwise indicated.

Symbol / Text	Meaning	Standard Reference
REF	Catalogue/Reference Number	ISO 15223-1:2021 §5.1.6
SN	Serial Number	ISO 15223-1:2021 §5.1.7
LOT	Lot/Batch Number	ISO 15223-1:2021 §5.1.5
⚠	Warning/Attention — consult accompanying documents	ISO 15223-1:2021 §5.4.3 / ISO 7000-0434
MFR	Manufacturer	ISO 15223-1:2021 §5.1.1
MFR date (calendar icon)	Date of manufacture	ISO 15223-1:2021 §5.1.3
EC REP	Authorised Representative in the European Community	EU MDR 2017/745 Annex I §23.4(a)

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MD	Medical Device (CE-marked, EU MDR 2017/745)	EU MDR 2017/745
UDI	Unique Device Identifier	EU MDR 2017/745 Article 27; ISO 15223-1 §5.1.9
IPX4	Protected against water splashing from any direction	IEC 60529
♻	Recyclable — dispose per local regulations	ISO 7000-1135
2×	Do not reuse / single-use (where applicable to accessories)	ISO 15223-1:2021 §5.4.2
Non-sterile symbol (crossed-out symbol)	Non-sterile — device is not supplied in a sterile state	ISO 15223-1:2021 §5.2.6
ECRHS-class-I symbol	Class I medical device — self-certified under EU MDR	EU MDR 2017/745 Article 52(7)

16. Manufacturer and Authorised Representative

Manufacturer (MFR)	EU Authorised Representative (EC REP)
Symmetric Designs Inc. Salt Spring Island, BC, Canada Tel: +1 250-537-1645 Email: info@symmetric-designs.com Web: www.symmetric-designs.com	**MedEnvoy Global B.V.** Prinses Margrietplantsoen 33 – Suite 123 2595 AM The Hague The Netherlands Tel: +31 70 326 2148 | info@medenvoyglobal.com

For post-market surveillance feedback, complaints, or technical support, contact Symmetric Designs Inc. directly using the details above. For EU vigilance and regulatory queries, contact the EU Authorised Representative (MedEnvoy Global B.V.).

17. Serious Incident Reporting

EU MDR 2017/745, Article 87 requires that healthcare professionals, patients, and users report serious incidents and field safety corrective actions to the relevant competent authority of the EU Member State in which they occurred.

A serious incident means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including errors of use due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer, which, directly or indirectly, has led to, or could lead to, the death of a patient, user, or other person, or to a temporary or permanent serious deterioration in the state of health of a patient, user, or other person, or to a serious public health threat.

If you experience or become aware of a serious incident involving this device:

24. Discontinue use of the device if it is safe to do so.
25. Ensure the safety and wellbeing of the patient first.
26. Preserve the device and all packaging in the condition at the time of the incident if possible.
27. Report the incident to the competent authority of your EU Member State.
28. Report the incident to Symmetric Designs Inc. at: sales@symmetric-designs.com (or the address in Section 16) and to MedEnvoy Global B.V. (EU AR, Section 16).

NOTE	In Canada, report adverse events to Health Canada's Medical Device Problem Reporting Program. In the USA, report to the FDA MedWatch programme. Contact Symmetric Designs for guidance on non-EU reporting procedures.

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18. Regulatory Declarations

18.1 European Union

The Savant Head Positioning System is a Class I medical device under EU MDR 2017/745, classified under Rule 1 (Annex VIII). As a Class I device, conformity has been assessed by Symmetric Designs Inc. under Article 52(7) without involvement of a Notified Body. A Declaration of Conformity (DoC) has been drawn up in accordance with Article 19 and Annex IV and is held on file; a copy is available on request from info@symmetric-designs.com.

The device is registered in EUDAMED (European Database on Medical Devices) in accordance with Article 29. The UDI is registered in accordance with Article 27.

18.2 Canada

Medical device distributed in Canada in accordance with the Medical Devices Regulations (SOR/98-282). Device Establishment Licence held by Symmetric Designs Inc. The Savant Head Positioning System is a Class I Medical Device; no device licence is required under Health Canada regulations.

18.3 United States

The Savant Head Positioning System is classified as a Class I 510(k)-exempt medical device (product code IOR) under 21 CFR Part 882. The device is exempt from premarket notification requirements.

18.4 Other Markets

The device is distributed internationally through an authorised distributor network. Regulatory status varies by jurisdiction. Contact Symmetric Designs or your regional distributor for country-specific regulatory information.

19. Document Control

Rev	Date	Author	Summary of Changes
A	2026-06-17	Symmetric Designs Inc.	Initial release
B	2026-06-17	Symmetric Designs Inc.	Revised to full EU MDR 2017/745 Annex I §23 compliance. Added: UDI block, EU AR details, residual risk disclosure, serious incident reporting (Art. 87), MDR classification rationale, accessories section, MRI safety, sterility/reuse declarations, storage conditions, EUDAMED reference.

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Annex A — EU MDR Annex I §23 Compliance Traceability Matrix

This annex documents traceability between the requirements of EU MDR 2017/745, Annex I, Section 23.4 and the sections of this IFU where each requirement is addressed. This matrix is an internal quality management reference and is part of the Technical Documentation for this device.

MDR Reference	Requirement	Addressed in IFU
§23.4(a)	Manufacturer name, registered trade name, address — including EU AR	✓ — Section 16

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§23.4(b)	Date of manufacture; where a batch, the batch code; where a series, the series code; where a model, the model or catalogue number	**✓ — Label / Section 2**
§23.4(c)	An unambiguous identification of the device enabling the device to be traced	**✓ — UDI block Section 2**
§23.4(d)	The word 'STERILE' or indication of sterile state, if applicable	**✓ — Non-sterile declared §4.4**
§23.4(e)	Any warnings or precautions to be taken	**✓ — Section 5**
§23.4(f)	If intended for single-use, that indication	**✓ — Reusable declaration §4.4**
§23.4(g)	If device is reusable, information on appropriate cleaning / disinfection	**✓ — Section 9**
§23.4(h)	Indication that the device is a custom-made device, if applicable	**N/A — not custom-made**
§23.4(i)	Indication that device is for clinical investigation, if applicable	**N/A**
§23.4(j)	Particular conditions for storage / handling	**✓ — Section 15**
§23.4(k)	Particular operating instructions	**✓ — Sections 7, 8**
§23.4(l)	Warnings and/or precautions regarding specific hazards	**✓ — Section 5**
§23.4(m)	Performance data and any undesirable side effects	**✓ — Section 4**
§23.4(n)	Information for the patient — implant card if applicable	**✓ — §4.5 (N/A, external device)**
§23.4(o)	Information for layperson	**✓ — Section 8 (caregiver instructions)**
§23.4(p)	If applicable: information about emission of ionising radiation	**N/A**
§23.4(q)	MRI / radiation safety information	**✓ — §4.6**
§23.4(r)	Accessories and other products to be used with device	**✓ — Section 12**
§23.4(s)	Date of issue or latest revision of IFU	**✓ — Cover / Section 19**
§23.4(t)	Information to allow HCP to inform patient of contraindications	**✓ — Section 6**
§23.4(u)	Residual risks communicated to user	**✓ — Section 5.3**
§23.4(v)	Freedom from known software hazards (if applicable)	**N/A — no software**
§23.4(w)	Serious incident reporting instruction	**✓ — Section 17**

All requirements of Annex I §23 that are applicable to this device have been addressed within this IFU. Requirements deemed not applicable are noted above with the basis for non-applicability.

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