



Declaration of Conformity

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| Document no: | P001_TF_09_Class I rev 01 |
| Manufacturer: | Swemac Innovation AB Cobolgatan 1 SE-583 35 Linköping Sweden |
| SRN: | SE-MF-000000727 |
| Conformity assessment route: | Drawing up the technical documentation set out in 93/42/EEC Annex VII and declaring conformity by signing the declaration of conformity |
| Intended purpose: | Re-usable surgical instruments intended for transient use. |
| Product: | Swemac Instruments |
| Valid from: | 2022-05-09 |
| Expiry date: | 2023-05-08 |

Product identification:

| Basic UDI-DI | UDI-DI | Article number | Article name | System | Risk class |
|-----------------|---------------|----------------|---|--|------------|
| 7340111750013R2 | 7340111751723 | 704511 | Guide Wire Bush 60 mm | Hansson Pin System | I |
| 7340111750013R2 | 7340111751082 | 60-3724 | Guide Wire Bush 60 mm | Hansson Pin System | I |
| 7340111750013R2 | 7340111751730 | 704526 | Guide Wire Bush 110 mm | Hansson Pin System | I |
| 7340111750013R2 | 7340111751099 | 60-3725 | Guide Wire Bush 110 mm | Hansson Pin System | I |
| 7340111750013R2 | 7340111751136 | 60-3767 | Drill Guide 6mm | Hansson Pin System | I |
| 7340111750013R2 | 7340111751143 | 60-3775 | Drill Guide 8mm | Hansson Pin System | I |
| 7340111750013R2 | 7340111751150 | 60-3783 | Drill Guide 10mm | Hansson Pin System | I |
| 7340111750006S4 | 7340111751884 | 704515 | Outer Introducer | Hansson Pin System | I |
| 7340111750006S4 | 7340111751211 | 60-3791 | Outer Introducer | Hansson Pin System | I |
| 7340111750006S4 | 7340111751891 | 704536 | Outer Introducer | Hansson Pin System | I |
| 7340111750006S4 | 7340111751228 | 60-3791B | Outer Introducer | Hansson Pin System | I |
| 7340111750006S4 | 7340111751907 | 704516 | Inner Introducer | Hansson Pin System | I |
| 7340111750006S4 | 7340111751235 | 60-3805 | Inner Introducer | Hansson Pin System | I |
| 7340111750006S4 | 7340111751914 | 704535 | Inner Introducer | Hansson Pin System | I |
| 7340111750006S4 | 7340111751242 | 60-3805B | Inner Introducer | Hansson Pin System | I |
| 7340111750010RT | 7340111751921 | 704517 | Introducer Handle | Hansson Pin System | I |
| 7340111750010RT | 7340111751259 | L4-1626 | Introducer Handle | Hansson Pin System | I |
| 7340111750007S6 | 7340111752027 | 704529 | Inner Extractor | Hansson Pin System | I |
| 7340111750007S6 | 7340111751334 | 60-3843 | Inner Extractor | Hansson Pin System | I |
| 7340111750007S6 | 7340111752034 | 704528 | Outer Extractor | Hansson Pin System | I |
| 7340111750007S6 | 7340111751341 | 60-3842 | Outer Extractor | Hansson Pin System | I |
| 7340111750010RT | 7340111752041 | 704527 | Extractor Handle | Hansson Pin System | I |
| 7340111750010RT | 7340111751358 | 60-3841 | Extractor Handle | Hansson Pin System | I |
| 7340111750013R2 | 7340111752065 | 60-2425 | Nonomiya Guide, Closed | Hansson Pin System | I |
| 7340111750013R2 | 7340111752072 | 60-2426 | Nonomiya Guide, Open | Hansson Pin System | I |
| 7340111750011RV | 7340111752119 | 62-3021 | Screwdriver 3,0 mm HEX with T-handle | Hansson Pinloc System | I |
| 7340111750013R2 | 7340111753918 | 62-3036 | Guide Wire sleeve Ø3,2 mm with Handle | Hansson Pinloc System, Dynaloc System Swemac THF System | I |
| 7340111750009SA | 7340111752171 | 62-3040 | Rescue Extractor Shaft | Hansson Pinloc System | I |
| 7340111750009SA | 7340111752188 | 62-3041 | Rescue Extractor Shaft - Part 2 | Hansson Pinloc System | I |
| 7340111750019SD | 7340111752195 | 62-3042 | Rescue Extractor Hammer | Hansson Pinloc System | I |
| 7340111750009SA | 7340111752201 | 62-3044 | Rescue Extractor Adapter - Pin Inner Thread | Hansson Pinloc System | I |
| 7340111750009SA | 7340111752218 | 62-3046 | Rescue Extractor Adapter - Pin Outer Thread | Hansson Pinloc System | I |

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|-----------------|---------------|------------|---|---|--|
| 7340111750009SA | 7340111752225 | 62-3048 | Rescue Extractor Adapter - Plate Inner Thread | Hansson Pinloc System | |
| 7340111750007S6 | 7340111752263 | 62-3064 | Pin Remover | Hansson Pinloc System | |
| 7340111750025S8 | 7340111752287 | 62-3070 | Awl | Hansson Pinloc System, Dynaloc System, Euloc Fixation System, Motec Wrist Prosthesis System | |
| 7340111750010RT | 7340111752379 | 62-3092 | Handle with Quick-Lock | Hansson Pinloc System, Dynaloc System, Swemac THF System | |
| 7340111750020RW | 7340111752393 | 62-3098 | Plate Fit Guide Wire Sleeve 120° | Hansson Pinloc System, Dynaloc System | |
| 7340111750013R2 | 7340111752430 | 62-3114 | Targeting Guide 6 mm 120° | Hansson Pinloc System, Dynaloc System | |
| 7340111750013R2 | 7340111752454 | 62-3116 | Targeting Guide 8 mm 120° | Hansson Pinloc System, Dynaloc System | |
| 7340111750013R2 | 7340111752478 | 62-3118 | Targeting Guide 10 mm 120° | Hansson Pinloc System, Dynaloc System | |
| 7340111750010RT | 7340111752508 | 62-3122 | Handle | Hansson Pinloc System, Dynaloc System | |
| 7340111750024S6 | 7340111752539 | 62-3125 | Screw | Hansson Pinloc System, Dynaloc System | |
| 7340111750013R2 | 7340111752584 | 62-4008 | Guide Wle Sleeve Ø3,2 mm | Hansson Pinloc System, Dynaloc System | |
| 7340111750013R2 | 7340111752607 | 62-4010 | Drill Sleeve Ø6,7 mm | Hansson Pinloc System, Dynaloc System | |
| 7340111750011RV | 7340111752614 | 62-4022 | T-handle 6,0 mm HEX | Hansson Pinloc System, Dynaloc System | |
| 7340111750020RW | 7340111753390 | 62-4018 | Plate Sizer | Hansson Pinloc System, Dynaloc System | |
| 7340111750013R2 | 7340111753925 | 62-4038 | Drill sleeve Ø6,7 mm with Handle | Hansson Pinloc System, Dynaloc System | |
| 7340111750013R2 | 7340111752232 | 62-3056 | Parallel guide, 6 mm | Hansson Pinloc System | |
| 7340111750013R2 | 7340111752249 | 62-3058 | Parallel guide, 8 mm | Hansson Pinloc System | |
| 7340111750013R2 | 7340111752256 | 62-3060 | Parallel guide, 10 mm | Hansson Pinloc System | |
| 7340111750011RV | 7340111752355 | 62-3086 | Plate Pusher / Drill Sleeve HEX | Hansson Pinloc System | |
| 7340111750020RW | 7340111752645 | 300.00.015 | Plate Inserter | Swemac THF System | |
| 7340111750013R2 | 7340111750580 | 200.00.050 | Centering Sleeve | Swemac THF System | |
| 7340111750009SA | 7340111750603 | 200.00.060 | Fixation Rod | Swemac THF System | |
| 7340111750011RV | 7340111750634 | 200.00.075 | Screwdriver 3,5 mm HEX | Swemac THF System | |
| 7340111750013R2 | 7340111750658 | 200.00.085 | Drill Guide & Tap Guide | Swemac THF System | |
| 7340111750020RW | 7340111750719 | 200.00.175 | Multi Angle Guide 130°, 135°, 140° | Swemac THF System | |
| 7340111750027SC | 7340111752737 | 200.00.235 | Retractor | Swemac THF System | |
| 7340111750013R2 | 7340111752744 | 200.00.320 | Nonomiya PEEK guide Ø3,2 mm | Swemac THF System | |
| 7340111750020RW | 7340111752751 | 200.00.240 | Multi Angle Guide 130°, 135°, 140° | Swemac THF System | |
| 7340111750021RY | 7340111752768 | 200.00.245 | Impactor | Swemac THF System | |
| 7340111750006S4 | 7340111751389 | 90-1201 | Inner Introducer | Swemac THF System | |
| 7340111750006S4 | 7340111751396 | 90-1202 | Outer Introducer | Swemac THF System | |
| 7340111750010RT | 7340111751402 | 90-1203 | Introducer Handle | Swemac THF System | |
| 7340111750007S6 | 7340111751419 | 90-1204 | Extractor | Swemac THF System | |
| 7340111750006S4 | 7340111751631 | 704602 | Inner Introducer | Swemac THF System | |
| 7340111750006S4 | 7340111751648 | 704606 | Introducer | Swemac THF System | |

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| 7340111750010RT | 7340111751655 | 704607 | Extractor Handle | Swemac THF System | |
| 7340111750007S6 | 7340111751662 | 704608 | Outer Extractor | Swemac THF System | |
| 7340111750007S6 | 7340111751679 | 704609 | Inner Extractor | Swemac THF System | |
| 7340111750006S4 | 7340111751686 | 704631 | Outer Introducer | Swemac THF System | |
| | 7340111751693 | 704620 | Removal Thread Device | Swemac THF System | |
| 7340111750026SA | 7340111751532 | 41-1730 | Tweezers for Cortical Screw | Motec Wrist Arthrodesis System, Swemac THF System | |
| 7340111750020RW | 7340111752546 | 200.00.305 | Medoff Guide | Medoff Sliding Plate System, Swemac THF System | |
| 7340111750027SC | 7340111750238 | 40-1503 | Hohmann Capitate Retractor | Motec Wrist Prosthesis System | |
| 7340111750021RY | 7340111750023 | 40-1516 | Impactor | Motec Wrist Prosthesis System | |
| 7340111750010RT | 7340111750207 | 40-1518 | Guide Wle T-Handle | Motec Wrist Prosthesis System | |
| 7340111750007S6 | 7340111750245 | 40-1519 | Cup Remover | Motec Wrist Prosthesis System | |
| 7340111750010RT | 7340111750221 | 40-2593 | Handle Tri-Lobe with Ratchet | Motec Wrist Prosthesis System | |
| 7340111750019SD | 7340111750252 | 52-2211 | Hammer | Euloc Fixation System, Motec Wrist Prosthesis System | |
| 7340111750010RT | 7340111750276 | 45-2585 | Handle Tri-Lobe with Quick-Lock | Bridge Basal Thumb Joint Prosthesis System, Euloc Fixation System, Motec Wrist Prosthesis System | |
| 7340111750026SA | 7340111752959 | 52-2100 | Parallel Pliers | Euloc Fixation System | |
| 7340111750011RV | 7340111752973 | 52-2217 | Screwdriver 2 mm Torx with Quick-Lock | Euloc Fixation System | |
| 7340111750021RY | 7340111752980 | 52-2203 | Impactor | Euloc Fixation System | |
| 7340111750007S6 | 7340111752997 | 52-2205 | Extractor | Euloc Fixation System | |
| 7340111750027SC | 7340111753017 | 52-2215 | Periost Elevator | Euloc Fixation System | |
| 7340111750024S6 | 7340111750900 | 41-1720 | Lock Screw for Drill Guide | Motec Wrist Arthrodesis System | |
| 7340111750011RV | 7340111750979 | 41-1740 | Screwdriver 2,5mm HEX with Quick-Lock | Motec Wrist Arthrodesis System | |
| 7340111750013R2 | 7340111751525 | 41-1752 | Drill Sleeve Ø4mm | Motec Wrist Arthrodesis System | |
| 7340111750013R2 | 7340111751006 | 41-1756 | Drill Guide for Nail | Motec Wrist Arthrodesis System | |
| 7340111750010RT | 7340111751501 | 49-2504 | Handle tri-Lobe with Quick-Lock | Motec Wrist Arthrodesis System | |
| 7340111750021RY | 7340111750290 | 45-2515 | Impactor Ø6 mm | Bridge Basal Thumb Joint Prosthesis System | |
| 7340111750011RV | 7340111750405 | 45-2582 | Screwdriver 3 mm HEX with Quick-Lock | Bridge Basal Thumb Joint Prosthesis System | |
| 7340111750012RX | 7340111753642 | 148-2030 | Wrench 6 mm and 3 mm | Bridge Basal Thumb Joint Prosthesis System | |
| 7340111750011RV | 7340111753659 | 148-2032 | Screwdriver 6 mm with Quick-Lock | Bridge Basal Thumb Joint Prosthesis System | |
| 7340111750026SA | 7340111751464 | 148-2038 | Forceps for Head and Cup | Bridge Basal Thumb Joint Prosthesis System | |
| 7340111750009SA | 7340111753895 | 150-3069 | Screw Holder | Dynaloc System | |
| 7340111750025S8 | 7340111753123 | 151.0001 | Curved Awl | Hansson DC Nail System | |
| 7340111750020RW | 7340111753482 | 151.2001 | Repositioning Guide | Hansson DC Nail System | |
| 7340111750013R2 | 7340111753130 | 151.2002 | Guide Sleeve for Opening Reamer | Hansson DC Nail System | |
| 7340111750030RZ | 7340111753536 | 151.6001 | Guide Wle for Opening Reamer | Hansson DC Nail System | |
| 7340111750010RT | 7340111753451 | 151.0002 | Guide Wle Driver - Handle | Hansson DC Nail System | |

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| 7340111750024S6 | 7340111753543 | 151.0003 | Guide Wle Driver - Screw | Hansson DC Nail System | |
| 7340111750024S6 | 7340111753567 | 151.4007 | Holding Bolt for Nail | Hansson DC Nail System | |
| 7340111750013R2 | 7340111753154 | 151.4002 | Targeting Device - Arm | Hansson DC Nail System | |
| 7340111750013R2 | 7340111753161 | 151.4003 | Targeting Device - Knob | Hansson DC Nail System | |
| 7340111750013R2 | 7340111753178 | 151.4004 | Targeting Device - Sleeve 120° | Hansson DC Nail System | |
| 7340111750013R2 | 7340111753185 | 151.4005 | Targeting Device - Sleeve 125° | Hansson DC Nail System | |
| 7340111750013R2 | 7340111753192 | 151.4006 | Targeting Device - Sleeve 130° | Hansson DC Nail System | |
| 7340111750011RV | 7340111753574 | 151.1001 | Ball Tip Screwdriver | Hansson DC Nail System | |
| 7340111750013R2 | 7340111753208 | 151.2003 | Guide Sleeve - Standard | Hansson DC Nail System | |
| 7340111750013R2 | 7340111753215 | 151.2004 | Threaded Guide Wle Sleeve | Hansson DC Nail System | |
| 7340111750013R2 | 7340111753222 | 151.2005 | Guide Sleeve - Biaxial | Hansson DC Nail System | |
| 7340111750013R2 | 7340111753239 | 151.2006 | Drill Sleeve Biaxial for Proximal Hole | Hansson DC Nail System | |
| 7340111750013R2 | 7340111753246 | 151.2007 | Drill Sleeve Biaxial for Distal Notch | Hansson DC Nail System | |
| 7340111750020RW | 7340111753581 | 151.4008 | Positioning Guide AP | Hansson DC Nail System | |
| 7340111750013R2 | 7340111753598 | 151.4009 | Positioning Guide AP - Tube | Hansson DC Nail System | |
| 7340111750020RW | 7340111753604 | 151.4010 | Positioning Guide ML | Hansson DC Nail System | |
| 7340111750011RV | 7340111753291 | 151.1002 | Lag Screw Driver - Shaft | Hansson DC Nail System | |
| 7340111750009SA | 7340111753307 | 151.1003 | Lag Screw Driver - Fixation Rod | Hansson DC Nail System | |
| 7340111750011RV | 7340111753314 | 151.1004 | Flexible Screwdriver | Hansson DC Nail System | |
| 7340111750013R2 | 7340111706099 | 151.2008 | Guide Sleeve for Locking Screw | Hansson DC Nail System | |
| 7340111750013R2 | 7340111706105 | 151.2009 | Drill Sleeve for Locking Screw | Hansson DC Nail System | |
| 7340111750030RZ | 7340111706112 | 151.2010 | Trocar Tip for Locking Screw | Hansson DC Nail System | |
| 7340111750011RV | 7340111753628 | 151.1005 | Screwdriver Bit | Hansson DC Nail System | |
| 7340111750021RY | 7340111753512 | 151.5001 | Strike Plate | Hansson DC Nail System | |
| 7340111750010RT | 7340111753345 | 151.0004 | T-Handle with Zimmer Hall Coupling | Hansson DC Nail System | |
| 7340111750021RY | 7340111753475 | 151.0005 | Guide Wle Pusher | Hansson DC Nail System | |
| 7340111750027SC | 7340111753468 | 151.0006 | Reduction Spoon | Hansson DC Nail System | |
| 7340111750007S6 | 7340111753635 | 151.5002 | Extraction Rod | Hansson DC Nail System | |
| 7340111750019SD | 7340111753529 | 151.5003 | Hammer with Slot | Hansson DC Nail System | |
| 7340111750011RV | 7340111753352 | 151.1006 | Self-Retaining Screwdriver | Hansson DC Nail System | |
| 7340111750010RT | 7340111753789 | 151.1007 | Handle with AO Coupling | Hansson DC Nail System | |
| 7340111750022S2 | 7340111753796 | 151.3009 | Lag Screw Tap | Hansson DC Nail System | |
| 7340111750017S9 | 7340111753802 | 151.0007 | Compression Device | Hansson DC Nail System | |
| 7340111750006S4 | 7340111753734 | 155.0001 | Inner Introducer | Hansson DC Nail System | |
| 7340111750006S4 | 7340111753741 | 155.0002 | Outer Introducer | Hansson DC Nail System | |
| 7340111750011RV | 7340111753758 | 155.1001 | Twin Hook Driver | Hansson DC Nail System | |
| 7340111750017S9 | 7340111753819 | 155.9001 | Compression Device for Twin Hook | Hansson DC Nail System | |

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| 7340111750017S9 | 7340111753826 | 155.9002 | Compression Device for Twin Hook - Counter part | Hansson DC Nail System | I |
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This Declaration of conformity is issued under the sole responsibility of Swemac Innovation AB. We hereby declare that the devices mentioned above are in conformity with Swedish medical device regulation LVFS 2003:11 transposing European Medical Devices Directive 93/42/EEC.

Linköping, 2022-05-09

See electronic signature

Andreas Sundberg, CRO

The following documents were signed Monday, May 9, 2022



P001_TF_09_Class I (reusable surgical instruments) rev 01 - Declaration of conformity.pdf

(241247 byte)
SHA-512: 59c904ee19bdc4e5579ed76aa3557478a7478
984db9394a70a2e1f2d8c3e15b502dec964f5916220296
a27a52ba11f71cd270dded7b09e0750317243efde7f5

Signatures

5/9/2022 3:33:54 PM (CET)



Andreas Sundberg, Approver

andreas.sundberg@swemac.com
Signed with electronic ID (BankID)



Signature is certified by Assently



DOC-2022-1685 - P001_TF_09_Class I (reusable surgical instruments) rev 01 - Declaration of conformity (revision 1)

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aa146b825dadcf93564c86db3583e969cbd6639401f1180f9e0a237d4468d290a1d03f3ba44350ef082df3779500626aeb4f88aec6c135840bfd166aee63be642



About this receipt

This document has been electronically signed using Assently E-Sign in accordance with eIDAS, Regulation (EU) No 910/2014 of the European Parliament and of the Council. An electronic signature shall not be denied legal effect and admissibility as evidence in legal proceedings solely on the grounds that it is in an electronic form or that it does not meet the requirements for qualified electronic signatures. A qualified electronic signature shall have the equivalent legal effect of a handwritten signature. Assently E-Sign is provided by Assently AB, company registration number 556828-8442. Assently AB's Information Security Management System is certified according to ISO/IEC 27001:2013.