Summary of Safety and Clinical Performance (SSCP)

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1 PURPOSE and SCOPE

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

The SSCP is not intended to replace the Instructions for Use, which are considered to be the main document to ensure the safe use of OsteoSinter® EVANS and COTTON wedges, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for **users/healthcare professionals**.

2 ABBREVIATIONS

SSCP	Summary of Safety and Clinical Performance
SRN	Single Registration Number
PMS	Post-Market Surveillance
PMCF	Post-Market Clinical Follow-Up
MD	Medical Device
SotA	State of the Art

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AAFD	Adult Acquired Flatfoot Deformities
GSPRs	General Safety and Performance Requirements
CS	Common Specifications

3 DEVICE IDENTIFICATION AND GENERAL INFORMATION

Table 1: Device identification and general information

Trade name of the device	OsteoSinter® EVANS and COTTON wedges and related accessories
Name and address of the manufacturer	AMES Medical Prosthetic solutions S.A.U Camí de Can Ubach, 8 Pol. Ind. "Les Fallulles" 08620 Sant Vicenç dels Horts Barcelona, Spain
Single registration number (SRN)	ES-MF-000000663
Basic UDI-DI	OsteoSinter® EVANS wedges: 8437019951p00100ewR7
	OsteoSinter® COTTON wedges: 8437019951p00100cwQZ
Medical device nomenclature description / text:	OsteoSinter® EVANS and COTTON wedges EMDN code: P091299
Class of device	OsteoSinter® EVANS and COTTON wedges: classified as class IIb according to Rule 8 from Annex VIII of REGULATION (EU) 2017/745
Year when the first certificate (CE) was issued covering the device	• Start of CE-Marking under the MDD CE certificate number: G1 104088 0001 Rev. 00 issued on 2020-03-05. • Start of CE-Marking under the MDR CE certificate number: G10 104088 0004 Rev. 00 issued on 2024-07-24. Additional devices (additional sizes) introduced: OsteoSinter® EVANS wedge 18W x 18L x 6H OsteoSinter® EVANS wedge 20W x 20L x 6H OsteoSinter® EVANS wedge 22W x 22L x 6H
Authorised representative if applicable; name and SRN:	N/A
Notified Body	TÜV SÜD Product Service GmbH Zertifizierstellen Ridlerstraße 65, 80339 MÜNCHEN, Germany +49 (89) 50084261 Identification number: 0123

4 INTENDED PURPOSE OF THE DEVICE

4.1. Intended purpose:

Implantable wedges for correction of foot deformities.

4.2. Indication(s) and target population(s):

4.2.1. Indications

OsteoSinter® EVANS and COTTON wedges are intended to be used for internal bone osteotomies in the foot. Specific indications include:

- Opening wedge of Medial Cuneiform or Cotton osteotomies.

- Lateral Column Lengthening (Evans Lengthening Osteotomy).

OsteoSinter® EVANS and COTTON wedges are not intended for use in the spine.

4.2.2. Intended target group

OsteoSinter® EVANS and COTTON wedges and related accessories should be used in patients undergoing correction of foot deformities.

4.2.3. Patient selection

Patient selection factors to be considered include:

- Good overall health of the patient.
- Good neurovascular status.
- Adequate skin coverage.
- Possibility of a functional musculotendinous system.
- Adequate bone stock to receive the implant.
- Full patient skeletal maturity.
- Co-operative patient; ability and willingness of the patient to follow post-operative care instructions until healing is complete.

4.3. Expected device lifetime

- OsteoSinter® EVANS and COTTON wedges: 3 months postoperative.
- Single-use OsteoSinter® EVANS and COTTON instrument kit: single-use.

4.4. Contraindications and/or limitations:

- Infection.
- Physiologically or psychologically inadequate patient (conditions that tend to limit the patient's ability or willingness to restrict activities or follow post-operative care instructions).
- Inadequate skin, bone or neurovascular conditions, which may delay healing.
- Growing patients with open epiphyses.
- Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to device implantation.
- Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.

5 DEVICE DESCRIPTION

5.1. Description of the device:

OsteoSinter® EVANS and COTTON wedges are titanium implants used to correct adult acquired flatfoot deformities, specifically for stage II posterior tibial tendon dysfunction. The wedges are intended to be used as an implant for an Evans procedure (for lateral column lengthening) or Cotton procedure (to improve the inclination of the first radius and avoid overloading the external column). These wedges make it possible to control the amount of lengthening or declination of the osteotomies. As the implant is highly porous, it induces the osteointegration of the surrounding bones through the interconnected porous parts which allow the implant to be firmly affixed unless unexpected infection or bone damage occurs (Figure 1). The surface of the implant in contact with the bone presents a relief that increases the friction coefficient with the aim of enhancing the primary fixation of the wedge.

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Figure 1: OsteoSinter® EVANS and COTTON wedges (scale not 1:1).

The implant is intended to be used with the associated instrument kit (accessory) in a surgical setting by a medical professional (traumatologist). The Single-use OsteoSinter® EVANS and COTTON instrument kit is made from Polyamide 12.

OsteoSinter® EVANS and COTTON wedge are supplied in a range of sizes (Table 2 and 3):

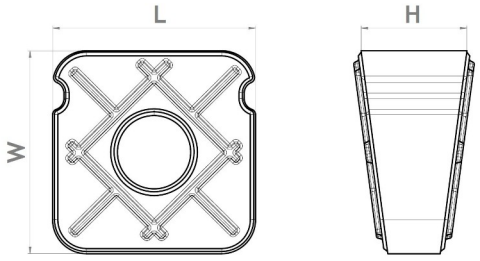

Table 2: OsteoSinter® EVANS wedge sizes.

Reference	**Name**	**W**idth (mm)	**L**ength (mm)	**H**eight (mm)
P00209A1	OsteoSinter® EVANS wedge 18W x 18L x 6H	18	18	6
P00200B1	OsteoSinter® EVANS wedge 18W x 18L x 8H	18	18	8
P00201B1	OsteoSinter® EVANS wedge 18W x 18L x 10H	18	18	10
P00202B1	OsteoSinter® EVANS wedge 18W x 18L x 12H	18	18	12
P00210A1	OsteoSinter® EVANS wedge 20W x 20L x 6H	20	20	6
P00203B1	OsteoSinter® EVANS wedge 20W x 20L x 8H	20	20	8
P00204B1	OsteoSinter® EVANS wedge 20W x 20L x 10H	20	20	10
P00205B1	OsteoSinter® EVANS wedge 20W x 20L x 12H	20	20	12
P00211A1	OsteoSinter® EVANS wedge 22W x 22L x 6H	20	20	6
P00206B1	OsteoSinter® EVANS wedge 22W x 22L x 8H	22	22	8
P00207B1	OsteoSinter® EVANS wedge 22W x 22L x 10H	22	22	10
P00208B1	OsteoSinter® EVANS wedge 22W x 22L x 12H	22	22	12

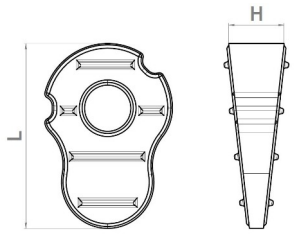

Table 3: OsteoSinter® COTTON wedge sizes.

Reference	Name	Length (mm)	Height (mm)
P00300B1	OsteoSinter® COTTON wedge 15L x 4.5H	15	4.5
P00301B1	OsteoSinter® COTTON wedge 15L x 5.5H	15	5.5
P00302B1	OsteoSinter® COTTON wedge 15L x 6.5H	15	6.5
P00303B1	OsteoSinter® COTTON wedge 20L x 4.5H	20	4.5
P00304B1	OsteoSinter® COTTON wedge 20L x 5.5H	20	5.5
P00305B1	OsteoSinter® COTTON wedge 20L x 6.5H	20	6.5

The implants and related accessories are supplied sterile, using gamma irradiation. Adequate packaging materials are used in order to permit terminal sterilisation and to protect the sterility of the device during its shelf-life. The implants and related accessories should be opened using an aseptic OR technique.

6 RISKS AND WARNINGS

6.1. Residual risks and undesirable effects:

The risk assessment has been carried out in accordance with ISO 17971.
As with any surgical procedure, there is potential for complications. The risks and complications (adverse events) with these implants include:

- Infection or pain, swelling or inflammation of the implant site.
- Fracture of the implant.
- Loosening or dislocation of the implant requiring revision surgery.
- Bone resorption or over-production.
- Allergic reaction to the implant material.
- Untoward histological responses possibly involving macrophages and/or fibroblasts.
- Migration of wear debris possibly resulting in a bodily response.
- Unwanted soft tissue damage and/or articular surface damage due to incorrect wedge placement.
- Embolism.

If any serious incident occurs in relation to the device, it should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
The expected frequencies of complications/adverse events come from a systematic review of the scientific literature within the Clinical Evaluation Report (CER) of the device. Table 4 shows a compendium of the complications/adverse events for a total of 491 implant placements over an average follow-up period of 25.1 months.

Table 4: Compendium of the complications and adverse events found and probability of occurrence.

Complication / adverse event	Cases (CER)	% (CER)	% OsteoSinter® EVANS and COTTON wedges
Pain	24	4.9%	0.12%
Revision surgery	16	3.3%	0

Arthritis	8	1.6%	0
Non-union	7	1.4%	0
Implant removal	7	1.4%	0
Lateral column overload	3	0.6%	0
Implant fracture	2	0.4%	0.09%
Recurrence	2	0.4%	0
Incorrect size	2	0.4%	0
Infection	3	0.6%	0.12%
Impaired healing	1	0.2%	0.12%
Implant malposition	2	0.4%	0.03%

According to the ongoing Non-interventional Observational Clinical Investigation carried out by the manufacturer, the above-mentioned complications/adverse events have not been reported (incidence rate 0% at 12 months follow-up). The benefits for the patients outweigh the residual risks.

6.2. Warnings and precautions:

Following the instructions for use provided can minimise the potential for complications or adverse reactions with any implant. It is the surgeon's responsibility to consider each patient's clinical and medical status and be knowledgeable about all aspects of the implant procedure and potential complications that may occur.

Specialised instruments have been designed for OsteoSinter® EVANS and COTTON wedges (Single-use OsteoSinter® EVANS and COTTON instrument kit) to assist with the accurate implantation of the prosthetic components. The use of instruments or implant components from any other system could result in an inaccurate fit, incorrect sizing, excessive wear and device failure. All instrument components must be removed prior to closing the surgical site. Do not implant.

OsteoSinter® EVANS and COTTON wedge devices cannot be expected to replace normal healthy bone, particularly in the presence of non-union, delayed union or incomplete healing. Therefore, it is important that immobilisation (use of external support, braces, etc.) of the fracture site be maintained until firm bony union is established (confirmed by clinical and radiographic examinations). Excessive, unusual and/or awkward movement and/or activity, trauma, excessive weight and obesity can cause premature failure of the implant by loosening, fracture, dislocation, subluxation and/or wear.

The surgeon must be thoroughly knowledgeable in the medical and surgical aspects of the implant and related instruments.

The main goal of surgery with this implant is to establish bone fusion. Surgical implants are subject to repeated stress during use, which can result in fatigue fracture. Abnormal or excessive force may lead to delayed union, non-union or failure of the implant. Abnormal force loading and subsequent wear may be caused by:

- Uncorrected instability
- Wrong size implant
- Inadequate soft tissue support
- Implant mispositioning
- Excessive motion
- Uncorrected or recurrent deformity
- Patient misuse or overactivity

Loads produced by weight bearing and activity may dictate the service life of the implant. IF EXCESSIVE LOADING CANNOT BE PREVENTED, AN IMPLANT SHOULD NOT BE USED.

The surgical technique should be followed. Deviations from the surgical technique may result in early loosening/failure of the device or other adverse events. Clinical outcome may be affected by component positioning. Proper placement of the implant should take into consideration individual patient anatomy as well as the surgeon's preference. The surgical technique gives guidelines for placement of the device.

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Proper primary fixation at the time of surgery is critical to the success of the procedure. Bone stock must be adequate to support the device. Some preventive measures to consider in order to minimise the potential for complications are:

• Follow the guidelines provided regarding indications and contraindications. Failure to use this device in accordance with the directions for use may result in device failure, render the device unsuitable for its intended use, or compromise the procedure.

• Identify prior pathology.

• Stabilise collapsed deformities.

• Bone graft pre-existing cysts.

• Use a properly sized implant. Correct selection of the implant is extremely important. The potential for success is increased by selecting the proper implant size and design. The patient's anatomy and indication will determine the size of the wedge to be used. The size and shape of human bones present limiting restrictions on the size and strength of implants. Avoid overcorrection because it could cause stiffness, lateral column overload and excessive plantar flexion.

• Do not reuse this device. This is a single-use device. Reuse of this product may result in infection or other systemic complications that may affect the patient's overall health. Additionally, the reuse of this product could adversely affect the performance of the device. Any implant that has been damaged, mishandled or removed from the sterile field may have surface damage that could result in implant fracture and/or particle release and should be discarded.

• Do not resterilise this device. The device is delivered sterile. This implant has been sterilised by gamma radiation and is sterile in the unopened, undamaged package. If either the implant or the packaging appears to be damaged, is beyond the sterility expiry date or if sterility is questioned for any reason, the implant should not be used. Resterilisation could lead to mishandling and surface damage that could result in implant fracture and/or particulate debris.

• Do not use implants or instruments after their expiry date.

• Avoid K-wires and sutures through the implant.

• Avoid flawing implant surfaces to minimise the potential for early fatigue failure. Correct handling of implants is extremely important. Do not modify implants. Notches or scratches made on the implants during the course of surgery may contribute to breakage.

Implant materials are subject to corrosion. Implanting metals subjects them to constant changing environments of salts, acids and alkalis that can cause corrosion. Putting dissimilar metals and alloys in contact with each other can accelerate the corrosion process that may lead to fracture of the implants. Every effort should be made to use compatible metals when mating components.

If complications develop, possible corrective procedures include:

• Implant removal

• Synovectomy

• Bone grafting of cysts

• Replacement of the implant

• Removal of the implant with fusion of the joint

Clinical results depend on the surgeon and technique, pre-operative and post-operative care, the implant, patient pathology and daily activity. It is important that surgeons obtain appropriate informed consent and discuss potential complications with the patient prior to surgery. The patient should be made aware of and warned about general surgical risks and possible adverse effects. The patient must be warned that non-compliance with post-operative instructions may increase the risk of device failure, as it could lead to breakage of the implant or fracture or osteotomy non-union requiring revision surgery to remove the device. The patient should be advised of the need for regular post-operative follow-up examinations as long as the implant remains in place. Surgeons must balance many considerations to achieve the best result in individual patients.

Recommendations regarding device fragments:

• Use medical devices in accordance with their labelled indications and instructions for use, especially during insertion and removal.

• Inspect devices prior to use for damage during shipment or storage or any out-of-box defects that might increase the likelihood of fragmentation during a procedure.

• Inspect devices immediately upon removal from the patient for any signs of breakage or fragmentation.

• If the device is damaged, please keep it to assist with AMES MEDICAL PROSTHETIC SOLUTIONS, S.A.U.'s analysis of the incident.

• Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs leaving the fragment in the patient.

• Advise the patient of the nature and safety of unretrieved device fragments including the following information:

a) The material composition of the fragment (if known);

b) The size of the fragment (if known);

c) The location of the fragment;

d) The potential mechanisms for injury, e.g. migration, infection.

The benefits derived from implant surgery may not meet the patient's expectations or may decrease with time, necessitating revision surgery to replace the implant or carry out alternative procedures. Revision surgery with implants is common. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure.

7 SUMMARY OF CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP (PMCF)

7.1. Summary of clinical data related to equivalent device, if applicable:

Not applicable.

7.2. Summary of clinical data from investigations of the device conducted before the CE marking, if applicable:

No clinical investigation was conducted before the CE marking.

7.3. Summary of clinical data from other sources, if applicable:

There is an ongoing Non-interventional Observational Clinical Investigation according to ISO 14155, which will not change the course of normal practice (no additional burdensome and/or invasive procedures are planned).

The clinical study is performed in order for the health professionals (traumatologists) participating in the study to know and evaluate the performance of OsteoSinter® EVANS and COTTON wedges. Likewise, the patients' post-surgical evolution will be assessed in order to evaluate the clinical and radiological results obtained with OsteoSinter® EVANS and COTTON wedges, a porous titanium implant, in reconstructive surgery for adult valgus flatfoot deformities.

Not all device references (total of 15 variants) will be evaluated considering the amount of patients to be recruited (20 patients). This gap is covered by the information retrieved from active post-market activities, i.e. surgeries performed implanting different references and their feedback (if any) have so far been positive. Also, the investigation protocol does not cover the three recently added EVANS wedge type references.

So far, evidence from the one-year follow-up of 11 patients shows that OsteoSinter® EVANS and COTTON wedges are safe and effective for correction of Stage II flatfoot deformity. The clinical data collected are as follows:

- Pre- and Post-operative functional AOFAS Ankle-Hindfoot score and SF-36 scores presented statistically significant improvement. The AOFAS score and SF-36 score showed a scoring mean improvement of 51 and 22%, respectively.

- The post-operative radiographic measurements are within the normal ranges according to the SotA (Meary's angle: 1.8±6.9º, Talocalcaneal divergence angle: 25.8±3º and Percentage of talonavicular uncoverage: 6.4±10%). Significant differences in radiographic parameters were found pre- and post-operatively (Meary's angle: Δ26º, Talocalcaneal divergence angle: Δ18.1º and Percentage of talonavicular uncoverage: Δ34%).

In addition, the preliminary results show:

- In the radiographic images 3 months after the interventions, there is no presence of peri-implant radiolucencies, no wedge migration and no evidence of non-union.
- No relevant incidents have been detected regarding the design of the Single-use OsteoSinter® EVANS and COTTON instrument kit.
- The implant does not cause any adverse effects on the patient.
- No ancillary fixations were required in any of the interventions.
- No wedges were removed due to continued pain at the osteotomy site.

The preliminary clinical results are satisfactory, and no significant complications have been reported to date. The evolution of the functional assessment and quality of life scales has been very good. In the radiological analysis of the reference angles, the improvement has been excellent.

When comparing the outcome measures of similar devices and those of the PMCF study, the clinical data on the performance and safety outcome parameters of the device under evaluation align with those identified in the SotA, confirming that the devices can be considered a state-of-the-art treatment for the medical conditions listed in the indications.

Table 5: Summary of outcome measurements from similar devices

Similar devices	Meary's Angle	Talonavicular coverage	Kite's Angle	AOFAS	SF-36	Radiographic outcome
Moore SH. et al.[1]	10.9 ± 5.6° / 5.6 ± 4.9° (Pre/Post) -Δ5.4º (50%)	37.6 ± 14.8° / 11.0 ± 14.8° (Pre/Post) -Δ26.6º (70%)	--		--	Radiographic evaluation of wedge position, integrity and union. No migration or structural failure was found
Matthews M. et al.[2]	5.20 ± 13.92° / 2.600 ± 6.22° (Pre/Post) -Δ13.9º (50%)	--	16.83 ± 7.56° / 12.58 ± 7.06° (Pre/Post) -Δ7.8º (25%)		--	100% bone union (absence of radiographic lucency surrounding the implant)
Gross CE. et al.[3]	15.2 ± 8.6° / 8.7 ± 7.7° (Pre/Post) -Δ7.1º (46.7%)	26.4 ± 9.6° / 14.0 ± 7.2° (Pre/Post) -Δ11.6º (44%)	--		--	Radiographically, union was defined as the lack of lines of lucency surrounding the implant on AP and lateral foot x-rays. Trabeculae were frequently seen integrating with and through the prosthesis. Clinically,

1 Moore SH, Carstensen SE, Burrus MT, Cooper T, Park JS, Perumal V. Porous Titanium Wedges in Lateral Column Lengthening for Adult-Acquired Flatfoot Deformity. Foot & Ankle Specialist. 2018;11(4):347-356. (p00100_cer-mdd-1)

2 Matthews M, Cook EA, Cook J, Johnson L, Karthas T, Collier B, Hansen D, Manning E, McKenna B, Basile P. Long-Term Outcomes of Corrective Osteotomies Using Porous Titanium Wedges for Flexible Flatfoot Deformity Correction. J Foot Ankle Surg. 2018 Sep-Oct;57(5):924-930. (p00100_cer-mdd-2)

3 Gross CE, Huh J, Gray J, Demetracopoulos C, Nunley JA. Radiographic Outcomes Following Lateral Column Lengthening With a Porous Titanium Wedge. Foot Ankle Int. 2015 Aug;36(8):953-60. (p00100_cer-mdd-3)

Similar devices	Meary's Angle	Talonavicular coverage	Kite's Angle	AOFAS	SF-36	Radiographic outcome
						union was defined as the lack of pain at the osteotomy site.
Romeo G. et al.[4]	9.5 ± 4.1 / 1.4 ± 1.9° (Pre/Post)	--	29.5 ±4.2 / 21.5 ± 2.5° (Pre/Post)	51.0 ± 20.7 / 90.2 ± 14.1 (Pre/Post)	--	
Tsai J. et al.[5]	−19.8° / −3.9° (Pre/Post) +Δ15.9º (80.3%)	31.6° / 12.5° (Pre/Post) -Δ19,1º (60.4%)	49.6° / 45.2° (Pre/Post) -Δ4.4º (8.9%)	--	--	No patient demonstrated loss of correction at the time of last radiographic follow-up
Fraser TW. et al.[6]	Δ15.9º	Δ24.5º	Δ8.5º	--	--	No complications, no evidence of non-union (no radiographic evidence of loosening or continued pain, no routine CT scanning was used)
Schleunes SD. et al.[7]	Δ9.9±5.0° (range -1.3 to 19.5°)	--	-Δ9.5° [median 8.0] (range -27.9 to 14.7°)	--	--	Non-union defined as lack of bony healing at the osteotomy site at 9 months confirmed by CT, if applicable, based on symptoms and radiographic findings
García-Jarabo E. et al.[8]	15.7 ± 3.4° / 3.1 ± 2.2° (Pre/Post)	21.3 ± 5.4° / 7.3 ± 3.4° (Pre/Post)	--	52 ± 10 / 88 ± 6 (Pre/Post)	--	Degree of wedges integration, the appearance of osteolysis and radiolucency. Adequate osteotomy integration was observed in all cases
Raikin S. M. et al.[9]	Pre-op. 30.2 ± 6.4° / 26.2 ± 5.7° (spring ligament – SL – tear / intact)	--	--	--	--	
Brian Au. et al.[10]	--	--	--	--	--	Non-union for the purposes of this study

4 Romeo G, Bianchi A, Cerbone V, Parrini MM, Malerba F, Martinelli N. Medial Cuneiform Opening Wedge Osteotomy for Correction of Flexible Flatfoot Deformity: Trabecular Titanium vs. Bone Allograft Wedges. Biomed Res Int. 2019 Mar 31;2019:1472471. (p00100_cer-mdd-19)

5 Tsai J, McDonald E, Sutton R, Raikin SM. Severe Flexible Pes Planovalgus Deformity Correction Using Trabecular Metallic Wedges. Foot & Ankle International. 2019;40(4):402-407. (p00100_cer-mdd-27)

6 Fraser TW, Kadakia AR, Doty JF. Complications and Early Radiographic Outcomes of Flatfoot Deformity Correction With Metallic Midfoot Opening Wedge Implants. Foot Ankle Orthop. 2019 Sep 11;4(3):2473011419868971. (p00100_cer-mdd-36)

7 Schleunes SD, Campbell SN, Jones JM, Philp FH, Catanzariti AR. Radiographic Analysis of the Lateral Column Lengthening Procedure in Stage II Adult Acquired Flatfoot Deformity. J Foot Ankle Surg. 2022 Nov-Dec;61(6):1293-1298. (p00100_4.1.30-1-6)

8 García-Jarabo E, Ramos-Ramos LM, Sánchez-Morata EJ, Hernanz-González Y, Mellado-Romero MÁ, Vilá Y Rico J. [Translated article] Surgical treatment at adult acquired flatfoot stage IIB: Spring ligament repair. Rev Esp Cir Ortop Traumatol. 2023 Jan-Feb;67(1):T62-T67. English, Spanish. (p00100_4.1.30-1-7)

9 Raikin, S. M., Rogero, R. G., Raikin, J., Corr, D. O., & Tsai, J. (2021). Outcomes of 2B adult acquired flatfoot deformity correction in patients with and without spring ligament tear. *Foot & Ankle International*, *42*(12), 1517-1524. (p00100_cer-mdd-56)

10 Au Brian, Patel NB, Smith CN, Burns PR. Short- to Intermediate-Term Radiographic Outcomes Following Cotton Osteotomy. J Foot Ankle Surg. 2022 Jul-Aug;61(4):812-820. (p00100_4.1.30-1-11)

Similar devices	Meary's Angle	Talonavicular coverage	Kite's Angle	AOFAS	SF-36	Radiographic outcome
						was determined with radiographic signs of non-incorporation of the graft at 9 months with or without persistent pain at the surgical site

So far no serious reportable adverse events have been reported to the competent authorities for the device under evaluation. The PMS feedback (if any) to date has been positive.
The clinical data gathered thanks to the activities performed in PMCF confirms the safety of the MD and its performance. No new hazards have been identified from data gathered from similar devices.

7.4. An overall summary of the clinical performance and safety:

The benefit/risk profile is acceptable according to current knowledge/SotA in the medical fields concerned (Adult Acquired Flatfoot Deformities) and it represents a good alternative to other available options, such as autograft or allograft.

The clinical benefits of using the device under assessment are direct and indirect. These clinical benefits cover all the indications of the device OsteoSinter® EVANS and COTTON wedge. The direct benefits are its therapeutic function in reducing the pain of patients with AAFD and their return to an active lifestyle.

Table 6: Clinical benefits.

CLINICAL BENEFITS	OUTCOME		
Description	Parameter	Outcomes measures	Success rate based on on-going non-interventional observational clinical investigation
Therapeutical function: reduction of pain	Reduction of pain: AOFAS Ankle-Hindfoot Score	Statistically significant improvement pre/post	100% statistically significant improvement in the AOFAS score.
		Calculated threshold for AOFAS: scores between 48 and 71	91% of the patients above the threshold.
Therapeutical function: return to an active lifestyle (novery strenuous or high-impact activities) and correction of deformities	Reduction of pain: Short Form-36 (SF-36) health survey	Statistically significant improvement pre/post	100% statistically significant improvement in the SF-36 score.
		Calculated threshold for SF-36: scores between 37% and 63%	91% of the patients above the threshold.
	Reduction of pain: AOFAS Ankle-Hindfoot Score	Statistically significant improvement pre/post	100% statistically significant improvement in the AOFAS score.
		Calculated threshold for AOFAS: scores between 48 and 71	91% of the patients above the threshold.
	Reduction of pain: Short Form-36 (SF-36) health survey	Statistically significant improvement pre/post	100% statistically significant improvement in the SF-36 score.
		Calculated threshold for SF-36: scores between 37% and 63%	91% of the patients above the threshold.
	Meary's Angle	Statistically significant improvement pre/post.	100% statistically significant improvement.
		Correction to normal values: between -4° to +4°	73% of the post-operative angles within the range.
	Talocalcaneal divergence angle	Statistically significant improvement pre/post	100% statistically significant improvement.

		Correction to normal values: between 25° and 40°	91% of the post-operative angles within the range.
	Percentage of talonavicular uncoverage	Statistically significant improvement pre/post	100% statistically significant improvement.
		Correction to normal values: <30%	91% of the post-operative percentages below the limit.
No loss of correction due to excessively rapid absorption	Type of material	Non-absorbable	100%
No need to shape the wedge.	Wedge design	Pre-defined sizes	
One procedure (foot site) instead of two (foot and donor sites, usually, iliac crest)	Type of material	No need for harvesting	
No donor site morbidity as seen with autografts	Type of material	No need for harvesting	
Instruments (sizers) to assist accurate implantation	Cases of overcorrection / undercorrection	No cases of overcorrection / undercorrection	
Reduction of OR time (thanks to benefits #B4, #B5), less time with the patient under general anaesthesia	OR time	<1h	
Reduction in the risk of infection (thanks to benefits #B4, #B5, #B8, #B9)	Wedge-related infection	1%	100%

Indirect benefits include avoid ing correction loss due to excessively rapid absorption (as seen with bone grafts), the reduction in OR time thanks to the fact that there is no need to shape the wedge and there is only one procedure instead of two, as needed for autografts. Since the material is non-absorbable, the wedges are available in a variety of sizes (there is a single-use instrument kit to assist with the implantation of the wedges, allowing the surgeon to define the right implant size) and there is no need for harvesting (as observed with autograft), the success rate for achieving the outcome measures is considered 100%.

The reduction in OR time translates into less time with the patient under general anaesthesia as well as a reduction in the risk of infection.

There are no special design features that pose particular safety concerns (e.g. presence of medicinal, human or animal components). A biological evaluation was satisfactorily executed, according to the EN ISO 10993 series, confirming the safety profile of the device under assessment. The risks identified in the Risk Management documentation and literature have been adequately addressed. The hazards and other clinically relevant information (e.g. clinical precautions for reduction of risks, clinical management of risks) have been identified appropriately.

Table 7: Clinical performance and safety criteria claimed.

#	Claim description	Claim achievement rationale		
		Parameter	***Expected result***	***Results***
C1	**Correction** of AAFD	Meary's Angle	±4º	1.8±6.9º (Post-op) Δ26±16.8º (improvement)
		Talocalcaneal divergence angle	25 – 40º	25.8±3º (Post-op) Δ18.1±8.3º (improvement)
		Talonavicular uncoverage percentage	<30%	6.4±10% (Post-op) Δ34.5±13.1% (improvement)
		Bone union by radiography (x-rays) and CT scan technology	Bone union, no peri-implant radiolucencies, no	Bone union, no peri-implant radiolucencies, no wedge migration

			wedge migration See thresholds in the CEP	See thresholds in the CEP
C2	Highly **porous**	Porosity range: 62 – 66% to mimic cancellous bone		
C3	**Osteointegration** of the surrounding bones through the interconnected porous material	As in claim #C1 (bone union), the clinical data gathered so far show the osteointegration of the wedge. The results of OsteoSinter® *in-vivo* studies are similar to those reported by benchmark devices and in line with the state of the art on porous metallic wedges, thus concluding that OsteoSinter® is osteointegrable.		
C4	Firmly **fixed** unless unexpected infection or bone damage occurs	The OsteoSinter® porous structure and the relief shape of the surfaces provide high primary fixation to the bone: • Abrasion properties: similar to benchmark devices. • Frictional properties: initial wedge stability, minimising micro-motion and creating a stable environment for rapid bone ingrowth and fixation, similar to benchmark devices. • Expulsion test: the wedges have good resistance to migration.		
C5	OsteoSinter® exhibits a **mechanical behaviour** similar to trabecular bone	• Apparent Elastic Modulus and Compressive yield strength similar to cancellous bone. • Compared to physiological loads, mechanical behaviour achieved a safety factor of at least 7.32 in the case of static tests, and a safety factor of 2.27 in the case of fatigue testing.		
C6	**Biocompatible** and **no toxic risk**	The biological evaluation of the implantable device has demonstrated that it is biologically and toxicologically safe for both the patient and the user; including chemical composition, *in-vitro* studies and the strictly required *in-vivo* animal testing according to ISO 10993-1.		
C7	Allows very precise control of the **amount of lengthening or declination** of the osteotomies	Pre-defined wedge sizes: system of variants (in terms of size and inclination) similar to benchmark devices.		
C8	Auxiliary **cavity** (hole) to allow a biological supplement to be incorporated (allograft)	Pre-defined hole at the centre of each wedge, similar to benchmark devices.		
C9	**Instruments** (sizers, tweezers, impactor) to assist with accurate implantation	The post-market activities have demonstrated so far that the instruments allow precise assistance with the interventions performed: this has also been reported in the usability studies.		
C10	Allows for an aseptic presentation (intended use environment is the operating room)	Sterile barrier system with protective packaging inside allows for an aseptic presentation.		
C11	**Sterile and single-use** compared to reusable instruments, thus avoiding delays, wear and storage issues at the clinical facilities (i.e. hospital)	The wedges and related accessories are supplied sterile by gamma radiation. Sterile, single-use instruments avoid delays (available at all times), wear, storage issues at the clinical facilities (i.e. hospital), as well as limiting infections and cross-contamination (improving patient safety).		
C12	Shelf life (expiry date) of 5 years	Performance data supports the shelf life by demonstrating continued sterility of the device, package integrity and device functionality over 5.3 years.		

The benefits of porous titanium wedges for the correction of the deformity (pain relief and a high rate of union) have been demonstrated in the literature for similar devices and confirmed by the clinical data from PMCF. The results are comparable to the use of autografts or allografts, thus representing an effective alternative.

Most of the clinical risks are limited to the safety and efficacy of the materials that make up the medical device, which have been thoroughly evaluated in the biological evaluation, and its performance, verified by bench testing.

A comprehensive analysis of the known and foreseeable potential hazards associated with the OsteoSinter® EVANS and COTTON wedges and related accessories was carried out (Risk Management and Clinical evaluation report), estimating the risks of each hazardous situation by means of published standards, technical data, data from similar products already in use, usability tests, expert opinion, etc. and taking into

account the life cycle of the medical device. Control measures have been implemented to reduce the risks either by inherently safe design, by providing protection and control measures in the manufacturing process and/or by providing safety information. None of the residual risks are within the non-acceptable area.

The safety characteristics and intended purpose of the device do not require training of the end-user. Nevertheless, as described in the IFU "*The surgeon must be thoroughly knowledgeable in the medical and surgical aspects of the implant and related instruments*".

There is consistency between current knowledge/SotA, the available clinical data, the information materials supplied by AMES Medical Prosthetic Solutions and the Risk Management documentation for the device.

The residual risks constitute acceptable risks when weighed against the benefits for the patient and are compatible with a high level of protection of health and safety, taking into account the SotA.

The lifetime of the device under assessment is considered to be once bony union is achieved. Considering that OsteoSinter® has a high friction coefficient with evidence of its grip to the bone enabling initial stability, its mass loss values are significantly lower than other coatings used in clinical applications. The results of the expulsion test suggest that the device has good resistance to migration, presents suitable osteointegration capabilities and fatigue testing corroborates the mechanical performance of the device, i.e. that it withstands physiological loads and the lifetime of the device is achievable and considered safe.
Nevertheless, the IFU warns the user about the importance of maintaining patient foot immobilisation until firm bony union is established, and the clinical data reported so far have shown that, during the lifetime of the device, its characteristics and performance are not adversely affected, neither is the health or safety of the patient, confirming the findings from the animal studies and bench testing.

The undesirable side effects are considered acceptable. Any surgical intervention presents its own risks, but considering the surgical treatment for correcting AAFD, the literature shows a complication percentage of around 20%[11]. Also, when comparing the side effects of benchmark devices, all of them present similarities and share the following complications: infection, loosening, implant fracture, pain and allergy, among others, which the IFU provided with the medical device also details. Nevertheless, the benefits for patients outweigh the residual risks for the indications detailed in the IFU.

The information materials supplied, the intended purpose, usability aspects and risk mitigation measures are adequate considering the intended users.

The claims foreseen are solid, in line with the claims from benchmark devices and are backed by evidence. The clinical evidence demonstrates conformity with the relevant GSPRs, the performance and safety of the device as claimed have been established and the risks associated with use of the device are acceptable when weighed against the benefits for the patient.

7.5. Ongoing or planned post-market clinical follow-up

Post-market activities have been scheduled in order to continuously gather clinical data from the use of the device under evaluation and provide evidence of its performance and safety profile (Table 8).

Table 8: Post-market activities that will be conducted in according to the Post-Market Clinical Follow-up Plan.

Origin of the need	Activities that will be conducted in post-market
Clinical Evaluation Report PMS Risk Management File Previous PSUR	Screening of the scientific literature and other sources of clinical data. Collecting data: any possible evaluation of suitable national public registries with clinical data on the medical device and/or on similar devices Literature search to provide evidence on the benefits of single-use instruments.

[11] Obey MR, Johnson JE, Backus JD. Managing Complications of Foot and Ankle Surgery: Reconstruction of the Progressive Collapsing Foot Deformity. Foot Ankle Clin. 2022 Jun;27(2):303-325. (p00100_4.1.30-1-12)

Clinical Evaluation Report PMS Risk Management File	Ongoing Non-interventional Observational Clinical Investigation as part of the Post-market Clinical Follow-up according to ISO 14155.
PMS Risk Management File	Customer feedback: **complaints** that may arise from the use of the medical device. Data collected during **attendance at surgeries** and cadaveric or biomodel workshops.
Clinical Evaluation Report PMS Risk Management File	Customer feedback: **Surveys** planned to collect information about the use of the medical device
Regulation (EU) 2017/745	Safety **communications** for reporting to the regulatory authorities
PMS Risk Management File	Incidents related to eIFU

During PMCF activities, no new hazards have been identified from the data gathered for similar devices and no emerging risks, complications or unexpected device failures have been detected.

8 POSSIBLE DIAGNOSTIC OR THERAPEUTIC ALTERNATIVES

There are numerous surgical options for AAFD, and in order to maintain the correction, an interpositional graft is placed within the osteotomy. Methods of correction include: tricortical iliac bone graft[12,13,14], allograft, xenograft, wedge locking plates, screw fixation and trabecular metal wedges[12,15,16].

A significant incidence of complications has been reported with iliac crest graft e.g. 16.5% pain at harvest site, 29.1% numbness, 3.9% scarring and 15.1% difficulty walking and 5.9% irritation from clothing[12]. Moreover, significant morbidity has been associated with harvesting structural bone grafts from the iliac crest[17].

The rate of major and minor complications related to iliac crest graft at the anterior iliac crest donor site has been reported as 5.3% and 25%[14], respectively. Major complications included residual numbness, abdominal hernia, residual pain, harvest site herniation and iliac wing fracture after harvest[14]. Minor complications were defined as superficial haematomas, temporary sensory disturbances and mild pain. Other potential complications include infection and fracture.

The morbidity associated with an iliac crest graft is well described in the literature. In the immediate postoperative period, it causes significant pain, discomfort and increased analgesic requirement. In the long-term, it can cause chronic pain, numbness, a decrease in activity as well as the effect of scarring on the cosmetic outcome[12].

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12 Mohamed KMS, Fenelon C, Galbraith JG, D'Souza LG. Obtaining local bone graft for Evans calcaneal osteotomy in pes planovalgus deformity correction. Foot Ankle Surg. 2017 Sep;23(3):208-210. (p00100_4.1.30-7-6)

13 Mosier-Laclair, Susan & Pomeroy, Gregory & Manoli, Arthur. (2001). Operative treatment of the difficult stage 2 adult acquired flatfoot deformity. Foot and ankle clinics. 6. 95-119. 10.1016/S1083-7515(03)00083-4. (p00100_4.1.30-7-18)

14 Grier KM, Walling AK. The use of tricortical autograft versus allograft in lateral column lengthening for adult acquired flatfoot deformity: an analysis of union rates and complications. Foot Ankle Int. 2010 Sep;31(9):760-9 (p00100_4.1.30-7-22)

15 Siegel M, Bode L, Brandenburg LS, Frodl A, Schmal H, Kühle J. Individual Concepts in Foot Surgery: A Comparison of Xenogeneic and Autologous Bone Grafts Used in Adults for Lateral Calcaneus-Lengthening Osteotomy According to Evans. J Pers Med. 2022 Dec 30;13(1):95. (p00100_4.1.30-7-1)

16 Demetracopoulos CA, Nair P, Malzberg A, Deland JT. Outcomes of a Stepcut Lengthening Calcaneal Osteotomy for Adult-Acquired Flatfoot Deformity. Foot Ankle Int. 2015 Jul;36(7):749-55. (p00100_4.1.30-7-23)

17 Grunander TR, Thordarson DB. Results of calcaneocuboid distraction arthrodesis. Foot Ankle Surg. 2012 Mar;18(1):15-8.(p00100_4.1.30-7-26)

Autografts are commonly preferred due to their osteoinduction, osteoconduction and osteogenicity characteristics. They are also preferred as they carry no immunogenic or disease transmission risk and better rates of incorporation in comparison to xenografts[12].

The collapse of the graft or non-union can lead to loss of correction[16].

Alternatives to allograft or autografting methods include the use of synthetic or engineered materials such as bioactive glass wedges[18] and metal wedges[1,5,19,20,21]. Titanium wedges have been used to avoid side effect of residual pain at the donor site and to ensure greater stability by eliminating the reabsorption phenomenon that sometimes occurs in bone grafts[4].

Potential advantages include: no donor site morbidity and pain seen with autograft, no potential risk of disease transmission as with allograft, no resorption followed by allograft or autograft collapse and easier availability for surgical centres.

The benefit/risk profile is acceptable according to current knowledge/SotA in the medical fields concerned (Adult Acquired Flatfoot Deformities) and it represents a good alternative to other available options, such as autograft or allograft.

9 SUGGESTED PROFILE AND TRAINING FOR USERS

The surgeon must be thoroughly knowledgeable in the medical and surgical aspects of the implant and related instruments.

10 REFERENCE TO ANY HARMONISED STANDARDS AND CS APPLIED

Table 9 and Table 10 detail the list of harmonised standards under the MDR (2017/745) and Directive 93/42/EEC, respectively (applied in full), as well as the relevant European Pharmacopoeia monographs adopted. No Common Specifications (CS) apply to this medical device.

The medical device meet the provision of the Regulation (EU) 2021/2226 as regards electronic instructions for use.

Table 9: List of MDR (2017/745) harmonised standards applied.

Harmonised standards	
CODE	**NAME**
EN ISO 13485:2016/AC:2018/A11:2021	*Medical devices - Quality management systems - Requirements for regulatory purposes.*
EN ISO 10993-9:2021	Biological evaluation of medical devices – Part 9: Framework for identification and quantification of potential degradation products
EN ISO 10993-10:2023	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
UNE-EN ISO 10993-12:2022	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
EN ISO 10993-17:2023	Biological evaluation of medical devices – Part 17: Toxicological Risk assessment of medical devices constituents
ISO 10993-18:2020 /Amd1:2022	Biological evaluation of medical devices – Part 18: Chemical characterization of materials
EN ISO 10993-23:2021	Biological evaluation of medical devices – Part 23: Test for irritation
UNE-EN ISO 14971:2020/A11:2022	Medical devices – Application of risk management to medical devices

[18] Borenstein T, Gonzalez T, Krevolin J, Den Hartog B, Thordarson D. Republication of "Preliminary Experience Using Bioactive Glass Wedges for Cotton Osteotomy". Foot Ankle Orthop. 2023 Aug 29;8(3):24730114231195358. doi: 10.1177/24730114231195358. PMID: 37669405; PMCID: PMC10469233 (p00100_4.1.30-16-4).

[19] Noble DM, Small B, Cooper MT, Park JS, Perumal V. Porous Titanium Wedges in Revision First Metatarsophalangeal Arthrodesis. Foot Ankle Orthop. 2022 Jan 21;7(1):2473011421S00378. (p00100_cer-mdd-83)

[20] Wapner K, Freeland E, Kirwan G, Baldwin K. A Retrospective Radiographic Evaluation of a Modified Method of Lateral Column Lengthening. Foot Ankle Spec. 2021 Oct;14(5):386-392. (p00100_cer-mdd-64)

[21] Carstensen S, Moore S, Park J, Cooper MT, Perumal V. Porous Titanium Wedges are an Alternative in Lateral Column Lengthening for Adult Acquired Flatfoot Deformity. *Foot & Ankle Orthopaedics*. 2018;3(3). (p00100_cer-mdd-20)

UNE-EN ISO 15223-1:2022	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
UNE-EN ISO 11137-1:2015/A2:2020	Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
UNE-EN ISO 11137-2:2015/A1:2023	Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose
UNE-EN ISO 14155:2021/A114:2024	Clinical investigation of medical devices for human subjects. Good clinical practice
EN ISO 11737-1:2018/A1:2021	Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2020	Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 14630:2024	Non-active surgical implants – General requirements
EN ISO 11607-1:2020/A1:2023	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems.
EN ISO 11607-2:2020/A1:2023	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.
EN 556-1:2024	Sterilization of medical device – Requirements for medical devices to be designated "STERILE" – Part 1: Requirements for terminally sterilized medical devices
European Pharmacopeia 11, 2.9.19	Particulate contamination: sub-visible particles (Method 1; Light Obscuration Particle Count Test, Test 1.B)
European Pharmacopoeia XI – 2.6.14	Bacterial endotoxins (Method D: Chromogenic kinetic method)

Table 10: List of Directive 93/42/EEC harmonised standards applied.

Harmonised standards	
CODE	**NAME**
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes.
EN ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 10993-3:2014	Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-6:2009	Biological evaluation of medical devices – Part 6: Tests for local effects after implantation
EN ISO 10993-9:2009	Biological evaluation of medical devices – Part 9: Framework for identification and quantification of potential degradation products
EN ISO 10993-11:2009	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
EN ISO 10993-12:2012	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
EN ISO 10993-17:2009	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
EN ISO 10993-18:2020	Biological evaluation of medical devices – Part 18: Chemical characterization of materials
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN ISO 11137-1:2015	Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11137-2:2015	Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose
EN ISO 11737-1:2006	Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products

EN ISO 14155:2020/A11:2024	Clinical investigation of medical devices for human subjects. Good clinical practice
EN ISO 14630:2009	Non-active surgical implants – General requirements
UNE-EN ISO 14602:2012	Non-active surgical implants – Implants for osteosynthesis – Particular requirements
EN ISO 16061:2009	Instrumentation for use in association with non-active surgical implants – General requirements
EN 62366:2008	Medical Devices. Part 1: Application of usability engineering to medical devices.
EN 1041:2009	Information supplied by the manufacturer of medical devices
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
EN 556-1:2001	Sterilization of medical devices – Requirements for medical devices to be designated "STERILE" – Part 1: Requirements for terminally sterilized medical devices

11 REVISION HISTORY

SSCP rev. number	Date issued	Description of change	Revision validated by the Notified Body
0	29/04/2024	Edition of the document	x Yes, validated by NB. This revision 0 comes from the document p00100_12.1.8-sscp-nb_rev4 validated by the NB. Validation language: English ☐ No
1	24/02/2025	Update of the standards and it has been indicated that the standards are applied in full. The CE certificate number under the MDR has been added and a typographical error on page 9 has been corrected. The changes have been managed according to p00100_4.1.9-93.	☐ Yes, validated by NB. x Not validated by NB.
2	13/05/2025	Update due to spelling mistakes, the changes have been managed according to p00100_4.1.9-96. Update the list of MDR harmonised standards applied. Update of the document according to p00100_4.1.32-cer_rev5. Update according to p00100_4.1.9-94.	☐ Yes, validated by NB. x Not validated by NB.
3	27/01/2026	Update according to ITA200220007953.	x Yes, validated by NB. Validation language: English ☐ Not validated by NB.
4	31/07/2026	Updated due to the revision of template 12.1.8 - template sscp_rev2 and the update of the list of standards. Updated according to p00100_4.1.32-cer_rev7.	☐ Yes, validated by NB. x Not validated by NB.