

SAM IO® Intraosseous Access System – EU MDR Classification Explanation

Following statement is explanation of EU MDR Classification of SAM IO® Intraosseous Access System and its components.

SAM IO® Intraosseous Access System is manufactured by ZIEN Medical Technologies.

The table below shows classifications of each component within the SAM IO® Intraosseous Access System.

Description	Quantity	Catalogue Number	Basic UDI-DI	Risk Classification with Rule	Notified Body Number
SAM IO® Needle Set	15 mm – 1 Pack, QTY 30	IO705W-1P	0850068519IO70XVL	Class IIa Rule 7	2862
	15 mm – 5 Pack, QTY 30 (6 x 5 packs)	IO705W-5P			
	25 mm – 1 Pack, QTY 30	IO706W-1P			
	25 mm – 5 Pack, QTY 30 (6 x 5 packs)	IO706W-5P			
	45 mm – 1 Pack, QTY 30	IO707W-1P			
	45 mm – 5 Pack, QTY 30 (6 x 5 packs)	IO707W-5P			
SAM IO® Stabilizer	1 pack, QTY 30	IO740-1P	0850068519IO740TJ	Class I Sterile, Rule 1	2862
	5 pack, QTY 30 (6 x 5 packs)	IO740-5P			
SAM IO® Driver	QTY 1	IO700	0850068519IO700T6	Class I, Rule 1	N/A
SAM IO® Adaptor	QTY 1	IO742	0850068519IO742TN	Class I, Rule 1	N/A

The SAM IO® Needle Set (Class IIa) and SAM IO® Stabilizer (Class Is) have been issued CE Certificates following a conformity assessment conducted by notified body Intertek.

The table below shows the catalogue numbers associated with the issued EC certificates.

Description	Catalogue Numbers	Basic UDI-DI	EC Certificate Number
SAM IO® Needle Set	IO705W-1P IO705W-5P IO706W-1P IO706W-5P IO707W-1P IO707W-5P	0850068519IO70XVL	28620212805
SAM IO® Stabilizer	IO740-1P IO740-5P	0850068519IO740TJ	28620212806

The SAM IO® Driver and SAM IO® Adaptor are considered accessories to the SAM IO® Needle Set. However, under Article 1, Section 4 of Regulation (EU) 2017/745, accessories to medical devices are also



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classified as medical devices. Accordingly, the SAM IO® Driver and SAM IO® Adaptor are classified as Class I medical devices.

As per Article 52, Section 7 of (EU) 2017/745, Class I medical devices are subject to self-certification by the manufacturer. A Declaration of Conformity must be prepared in accordance with Article 19. A Declaration of Conformity has been prepared by ZIEN Medical Technologies and is available for both the SAM IO® Driver and SAM IO® Adaptor.

Respectfully,

Angeles Fratti
ZIEN Regulatory Engineer
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