



ZIEN Medical Technologies

Title:

SAM® IO Declaration of Conformity [EN]

Number:

SAM10108.00

Revision:

B

Declaration of Conformity

MANUFACTURER	ZIEN Medical Technologies 2490 South 300 West Salt Lake City, UT, 84115, USA		
SRN OF MANUFACTURER	US-MF-000004717		
EUROPEAN REPRESENTATIVE	CS Life Sciences Europe Ltd, The Black Church, St. Mary's Place, Dublin 7, Dublin, D07P4AX, Ireland, eurep@cslifesciences.com		
SRN OF EUROPEAN REPRESENTATIVE	IE-AR-000004113		
BASIC UDI-DI	See attached schedule for multiple products		
PRODUCT NAME	SAM IO Intraosseous Access System		
CATALOGUE NUMBER	See attached schedule for multiple products		
RISK CLASSIFICATION WITH RULE	See attached schedule for multiple products		
INTENDED PURPOSE	The SAM® IO Intraosseous Access System provides intraosseous access in the proximal tibia, distal tibia and humeral head (proximal humerus) of adults and pediatric patients, and the distal femur in pediatric patients for up to 24 hours.		
COMMON SPECIFICATIONS AND STANDARDS APPLIED	There are no common specifications published for this device type.		
	Standards Applied		
	EN ISO 13485:2016/A11:2021	EN ISO 10993-11:2018	ISO 15223-2:2010
	EN ISO 14971:2019/A11:2021	EN ISO 10993-12:2021	EN ISO 20417:2021
	CEN ISO/TR 24971:2020	EN ISO 10993-18:2020	EN 62366-1:2015/A1:2020
	EN ISO 14155:2020	EN ISO 10993-23:2021	ASTM A313/A313M-18
	EN ISO 10993-1:2020	EN ISO 11607-1:2020/A1:2023	ASTM A632-04 R14
	EN ISO 10993-4:2017	EN ISO 11607-2:2020/A1:2023	EN ISO 9626:2016
	EN ISO 10993-5:2009	ASTM F1980-21	EN ISO 23908:2013
	EN ISO 10993-7:2008/A1:2022	EN ISO 15223-1:2021	EN ISO 7864:2016
	EN ISO 10993-10:2023	EN ISO 11135:2014/A1:2019	EN ISO 80369-7:2021
	EN 556-1:2001/AC:2006		
NOTIFIED BODY	Intertek Medical Notified Body AB Torshamnsgatan 43, Box 1103 SE-164 22 Kista Sweden NB 2862		
CONFORMITY ASSESSMENT PROCEDURE	Annex IX, QMS and technical documentation.		
CERTIFICATE NUMBER	28620212805 28620212806		

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DECLARATION STATEMENT

We herewith declare that this EU declaration of conformity is issued under the sole responsibility of ZIEN Medical. The device(s) covered by present EU declaration of conformity is in conformity with the European Union Medical Device Regulation 2017/745

PLACE OF ISSUE:

SALT LAKE CITY UTAH, USA

SIGNATURE



Adam Howell
VP Quality and Regulatory
Person Responsible for Regulatory Compliance
Signed for and on behalf of ZIEN Medical Technologies

2025/07/22
Date (YYYY/MM/DD)

Schedule of included devices

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 Driver is self-certified by ZIEN Medical Technologies and is an accessory to the SAM® IO Needle Set.