

SHOP PACKET - ANTI BIOFILM COATED ORTHOPAEDIC IMPLANT (ZNNTM Bactiguard[®] / ANNTTM Bactiguard[®] / Orthosyn[®])

REF. NO	FLS4872C	ORD. QTY	10	RS	0	ISSUED DATE	6-Sep-22
DESCRIPTION	Orthosyn, Ø4.8mm IM Nail Interlocking Screw, Size 72mm	REQUIRE DATE	10-Sep-22	MBN. NO	I2001 - 18	EXPIRY DATE	2027-09
CUSTOMER	VMS (MALAYSIA)	S/PKT LOT NO	I20509	INT. ORD	IO/VMS/050922/01	SUP. LOT NO	217636
CATEGORY	<input type="checkbox"/> Long Nails (LN) <input type="checkbox"/> Medium Nails (MN) <input checked="" type="checkbox"/> Screw (S)					SUP. GTIN NO	9555468913641
PREPARED BY	Name: NUR SHAHIRA Date: 6/9/2022	VERIFIED BY	Name: MUHD ARIFUDDEEN Date: 6/9/2022				

PROCESS	START	END	LOAD QTY PCS	OUTPUT QTY PCS	REJECT QTY PCS	OPERATOR	IPQC APPROVAL	REMARKS
SEGREGATION & VERIFICATION								REFER TO CHECKLIST SEGREGATION AND VERIFICATION (BEFORE LASER MARKING) : PR-BC004
DATE								
TIME								
FIBER LASER MARKING								
DATE	6/9/2022	6/9/2022	10	10	0	HAWAANIS(998) NABILA(1205)	Roshni 6/9/2022	REFER TO TE-PP029
TIME	2:57 pm	2:58 pm						
IMPLANT RACKING								REFER TO BG COATING RACKING PLAN PR-BC001
DATE								
TIME								
BG COATING								REFER TO PR-BC001
DATE								
TIME								
OVEN DRYING								REFER TO OVEN DRYING PLAN PR-BC001
DATE								
TIME								
SEGREGATION & VERIFICATION								
DATE	10/09/2022	10/09/2022	10	10	0	AMANI(1149)	Roshni 10/09/2022	N/A
TIME	3:42 pm	3:44 pm						
INNER POUCH / BLISTER LABELLING								REFER TO PR-BC006
DATE	10/09/2022	10/09/2022	10	10	0	NABILA(1205)	Roshni 10/09/2022	
TIME	3:44 pm	3:46 pm						
INNER POUCH / BLISTER SEALING								REFER TO PR-BC001
DATE	10/09/2022	10/09/2022	10	10	0	ISMA(1174)	Roshni 10/09/2022	
TIME	3:46 pm	3:48 pm						
OUTER BLISTER LABELLING								REFER TO PR-BC006
DATE								
TIME								
OUTER POUCH / BLISTER SEALING								REFER TO PR-BC001
DATE	12/09/2022	12/09/2022	10	10	0	ISMA(1174)	Hana 12/09/2022	
TIME	10:08 AM	10:10 AM						
GAMMA CARTON PACKAGING								REFER TO SH-PL007
DATE								
TIME								
SENDING FOR GAMMA IRRADIATION								REFER TO SH-PL007 & QC-OI001
DATE								
TIME								
RECEIVING AFTER GAMMA IRRADIATION								REFER TO QC-OI001
DATE								
TIME								
SHELF BOX LABELLING, PACKAGING & FINAL CONTROL								ONLY FINAL CONTROL
DATE	19/09/2022	19/09/2022	10	10	0	FARAH(1057) HEPPY(1178)	mimi 19/09/2022	
TIME	9:40 AM	9:44 AM						
SHELF BOX OVER WRAPPING								REFER TO TE-PP016
DATE								
TIME								

Note: 1. For Shipper Carton Packaging Information, Please Refer To Internal Packing List (Sterile) Orthopaedic Implant (SH-PL006 - Rev 01)

2. Nut and Washer falls under "Screw" category.

STERILIZATION

: GAMMA

STERILIZATION DATE

: 1 4 - 0 9 - 2 2

STERILIZATION BATCH NO.:

MY03212696870-1-1

RETAIN SAMPLE QTY

:

STERILE

ADILA NURSYIMA

15 SEP 2022

Checked by (PR),

Signature :

Name :

Date :

Remarks,

Release by (QC),

Signature :

Name :

Date :

Stamp :



Product Name: Φ 4.8mm IM Nail Interlocking Screw

Specifications: 72mm

Product Code: 21748072

Material: TA

Qty: 1



LOT 217636



ChangZhou NanXiang Medical Device Co., Ltd
Address: No. 23, Daoxiang Rd., Wujin Economic Development Zone
213149 Changzhou, Jiangsu PEOPLE'S REPUBLIC OF CHINA
TEL: +86-519-86380098 FAX: +86-519-86393587

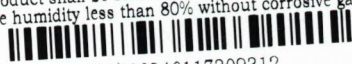
EC REP

MedNet EC-REP GmbH

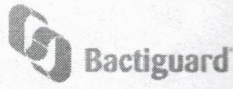
Address: Borkstrasse 10, 48163 Münster, Germany

The product shall be stored in well-ventilated room with
relative humidity less than 80% without corrosive gas.

CE 0123



(01)06946117309312

Title: QC IN-PROCESS INSPECTION RECORD – ANTI-BIOFILM COATED ORTHOPEDIC IMPLANT			
Document type: FORM	Doc Id: QC-IP003-5	Issue Date: 26/10/2021	Page: 1(9)

MBN No.	I2001-19		
Lot No.	I20509	Order Quantity	10

A. Fiber Laser Marking

Inspected by: Roshni

Product Category	Sampling Details	Sample Size	Inspection Criteria			Test Disposition (Pass / Fail)
			Marking information is correct and legible	Product marking is as PR-GU008	Implant is transferred into the pouch/other packaging after marking	
Long Nail						
Medium Nail				NA		
Screw	100%	10	✓	✓	✓	pass

B. Implant Racking

Inspected by: _____

Sampling / Frequency	No defects such as scratches and free from dirt / particles / foreign matters on implant	The implants are hanged on the rack with correct orientation	Test Disposition (Pass / Fail)
	Refer MBN No: I2001-19		

C. Implant Coating

Inspected by: _____

Sampling / Frequency	Ensure the racks/baskets pass through all the coating line by correct sequence number	Rack with nails directly hanged in the oven & smaller implants should be transferred into oven tray after completion of coating process	Test Disposition (Pass / Fail)
	Refer MBN No: I2001-19		

Remarks:

N/A