



EC Declaration of Conformity

Manufacturer:	<i>Aso Philippines Inc.</i> 4 th Street, Block D-5 Mactan Economic Zone 1 Lapu-Lapu City, Cebu Philippines SRN: Pending*
Whose European Representative:	<i>Aso Europe BV</i> Nijverheidstraat 48 6681 LN Bemmelen SRN: NL-AR-000004377
Importer:	<i>Aso Europe BV</i> Nijverheidstraat 48 6681 LN Bemmelen The Netherlands SRN: NL-IM-000004378

*Status per 26/05/21: company registered in EUDAMED, awaiting confirmation with SRN.

We hereby declare that the products mentioned in attachment 1 meet the provisions of (EU) MDR 2017/745 and are in compliance with ISO 13485 Standard for Medical devices. All supporting documentation is retained under the premises of the Manufacturer and Authorised Representative.

Notified Body <i>Name:</i> <i>ID:</i>	N/A
Certificate Number:	N/A
First Issue Date:	N/A
Expiration Date:	N/A

This Declaration of Conformity is issued exclusively under the responsibility of Aso Philippines Inc..

Place:	Nijmegen
Date:	26/05/2021
Name:	Helen Peemen
Function:	Manager QA/RA
Signature:	

Attachment 1:

Part Number Aso Philippines Inc.	Part Number Aso Europe BV	Part Number Distributor	Trade Name	Product name
Product family:		Tapes		
BASIC-UDI-DI:		48079990API093NG		
01-1801	01-1801	TBD	TBD	Blue Cohesive Bandage 3cmx7m
01-1802	01-1802	TBD	TBD	Blue Cohesive Bandage 5cmx7m
FM-50027	FM-50027	50027	Hygostar	Hygostar Blue Cohesive Bandage 3cmx7m - 1 roll <i>Contains: 01-1801</i>
FM-500279	FM-500279	500279	Hygostar	Hygostar Blue Cohesive Bandage 3cmx7m- 8 rolls <i>Contains: 01-1801</i>
FM-50028	FM-50028	50028	Hygostar	Hygostar Blue Cohesive Bandage 5cmx7m - 1 roll <i>Contains: 01-1802</i>
FM-500289	FM-500289	500289	Hygostar	Hygostar Blue Cohesive Bandage 5cmx7m- 8 rolls <i>Contains: 01-1801</i>
Intended Purpose:		To secure bandages, wound compresses and help keep out dirt and contaminants		
Classification:		Class 1 rule 4, according to Annex VIII of (EU) MDR 2017/745		
Common Specifications:		-		
Conformity Assessment Route:		Annex II, III, IV, V (EU) MDR 2017/745		
GMDN:		34830, 34830 (Paper tape only), 34084 (Cohesive tape only)		
EMDN:		TBD		



Helen Peemen
Manager QA/RA

24/11/2023
Date