EC Declaration of Conformity

Manufacturer:	*Aso Philippines Inc.* 4th Street, Block D-5 . Mactan Economic Zone 1 Lapu-Lapu City, Cebu Philippines ***SRN:** Pending**
Whose European Representative:	*Aso Europe BV* Bijsterhuizen 1160e 6546 AS Nijmegen The Netherlands ***SRN:** NL-AR-000004377*
Importer:	*Aso Europe BV* Bijsterhuizen 1160e 6546 AS Nijmegen 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 *Name:* *ID:*	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:	29/09/21
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:	***ADHESIVE PLASTERS***			
BASIC-UDI-DI:	***48079990M157QQ***			
39-0391	39-0391			Clear Watershield HD 25x76mm
39-0395	39-0395			Clear Watershield HD 50x100mm
LR-109841	LR-109841	109841	Forteplast	Forte Plast Pflstr 5x10 10 Stk *Contains: 39-0395*
LR-109930	LR-109930	109930	Forteplast	Forte Plast Pflstr 2,5x7,6 20 Stk *Contains: 39-0391*
Intended Purpose:		First- aid product to be used for absorption of exudes, compression or protecting wounds and wound surfaces		
Classification:		Class 1 rule 4, according to Annex VIII of (EU) MDR 2017/745		
Common Specifications:		No applicable CS available yet		
Conformity Assessment Route:		Annex II, III, IV, V of (EU) MDR 2017/745		
GMDN:		44990		
EMDN:		M0599		



29/09/21

Helen Peemen
Manager QA/RA

Date