



Instructions for Use -Not Provided

Bevaplast B.V.

The MDR requires that medical devices are provided with instructions for use. However, there is an exception that when the device can be used safely without instruction there is no need to add such instructions for use.

This statement is in line with REGULATION (EU) 2017/745 of 5 April 2017 on medical devices

MDR Annex I, Chapter III, 23.1.d: Instructions for use shall be provided together with the devices. By way of exception, instructions for use shall not be required for class I and class IIa devices if such devices can be used safely without any such instructions and unless otherwise provided in this Section.

The following devices will be delivered without instructions for use according to the Bevaplast internally established Standard Briefings regarding information supplied, **see Addendum 1**,

This statement is signed on behalf of Bevaplast B.V. , by:	
Name	Herre de Jong
Function	Manager QA & RA /PRRC
Place	Arnhem
Date	15-Jul-2021
Signature	

Manufacturer or Translator & Importer, see Addendum 1	
Name	Bevaplast B.V.
SRN	NL-MF-000004386
Address	Delta 170
Postal code	6825 MV
City	Arnhem
Country	The Netherlands



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Addendum 1 – Devices covered

The table below includes the device(s) covered according to our standard briefing text where no instructions for use are applicable according to the assessment performed according to EU MDR 2017/745 Annex I, Chapter III, 23.1.d:

Product names	Standard Briefing for information supplied as applicable]	Role Bevaplast
Wound Plasters	TD 09 STRXX	Manufacturer
Wound Plasters	TD 09 Wound plaster	Translator/importer
Skin Protection plasters	TD 09B Skin protection plasters	Translator/importer
Conforming Bandage	TD 10 ELBAN	Translator/importer
Cohesive Bandage	TD 14 COBAN 1.2	Manufacturer
Cohesive Bandage	TD 14 Cohesive Bandage	Translator/importer
Elastic sports bandage Ideal bandage Crepe Bandage	TD 14 XXWIN 1.6	Manufacturer
Medical Adhesive Tapes	Medical Adhesive Tapes	Translator/importer