



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 |