

# Novista of Sweden AB

## Declaration of Conformity

### **Manufacturers name & address**

Novista of Sweden AB

Org. nr. 556556-5206

Johannebergsvägen 6

SE-312 72 Skummeslövsstrand

Sweden

### **Object of the declaration**

As listed in attachment; *"Objects of Declaration"*

### **Declaration of conformity**

Novista of Sweden AB hereby confirm that the products listed in the attachment *"Objects of Declaration"* fulfil the applicable requirements of the EU-regulation MDR 2017/745 (with the exception of registration in EUDAMED) and of the Swedish law (1993:584) regarding medical products and regulations from the Swedish authority Läkemedelsverket, LVFS 2003:11 regarding medical products. Reference no. in Läkemedelsverket; 1590993669451

### **Correlation between regulations and directives**

Läkemedelsverkets regulations regarding medical products, LVFS 2003:11, correlates to the EU-directive regarding medical products, MDR 2017/745



**Emmy Kjell, CEO**

2020-08-05, Skummeslövsstrand

## Objects of Declaration

Attachment to "Declaration of Conformity"

Article No	Product	Classification
008131070	Weight Duvet Luna 150x200 cm, 4 kg	Class 1
008131071	Weight Duvet Luna 150x200 cm, 6 kg	Class 1
008131072	Weight Duvet Luna 150x200 cm, 8 kg	Class 1
008131073	Weight Duvet Luna 150x200 cm, 10 kg	Class 1
008131074	Weight Duvet Luna 150x200 cm, 12 kg	Class 1
008131075	Weight Duvet Luna 150x200 cm, 14 kg	Class 1
008131076	Weight Duvet Luna 110x125 cm, 2.3 kg	Class 1
008131077	Weight Duvet Luna 110x125 cm, 3.7 kg	Class 1
008131078	Weight Duvet Luna 110x125 cm, 5.0 kg	Class 1
008131080	Weight Duvet Futura 150x200 cm, 4 kg	Class 1
008131081	Weight Duvet Futura 150x200 cm, 6 kg	Class 1
008131082	Weight Duvet Futura 150x200 cm, 8 kg	Class 1
008131083	Weight Duvet Futura 150x200 cm, 10 kg	Class 1
008131084	Weight Duvet Futura 150x200 cm, 12 kg	Class 1
008131085	Weight Duvet Futura 150x200 cm, 14 kg	Class 1
008131086	Weight Duvet Futura 110x125 cm, 2.3 kg	Class 1
008131087	Weight Duvet Futura 110x125 cm, 3.7 kg	Class 1
008131088	Weight Duvet Futura 110x125 cm, 5.0 kg	Class 1
008131090	Weight Duvet Nova 150x200 cm, 4 kg	Class 1
008131091	Weight Duvet Nova 150x200 cm, 6 kg	Class 1
008131092	Weight Duvet Nova 150x200 cm, 8 kg	Class 1
008131093	Weight Duvet Nova 150x200 cm, 10 kg	Class 1
008131094	Weight Duvet Nova 150x200 cm, 12 kg	Class 1
008131095	Weight Duvet Nova 150x200 cm, 14 kg	Class 1
008131096	Weight Duvet Nova 110x125 cm, 2.3 kg	Class 1
008131097	Weight Duvet Nova 110x125 cm, 3.7 kg	Class 1
008131098	Weight Duvet Nova 110x125 cm, 5.0 kg	Class 1
008131160	Weight Duvet Safir 150x200 cm, 4 kg	Class 1
008131161	Weight Duvet Safir 150x200 cm, 6 kg	Class 1
008131162	Weight Duvet Safir 150x200 cm, 8 kg	Class 1
008131163	Weight Duvet Safir 150x200 cm, 10 kg	Class 1
008131164	Weight Duvet Safir 150x200 cm, 12 kg	Class 1
008131165	Weight Duvet Safir 150x200 cm, 14 kg	Class 1
008131166	Weight Duvet Safir 110x125 cm, 2.3 kg	Class 1
008131167	Weight Duvet Safir 110x125 cm, 3.7 kg	Class 1
008131168	Weight Duvet Safir 110x125 cm, 5.0 kg	Class 1
008131030	Hygiene Cover 150x200 cm	Class 1
008131031	Hygiene Cover 110x125 cm	Class 1
008131035	Hygiene Cover 140x200 cm	Class 1

<b>Article No</b>	<b>Product</b>	<b>Classification</b>
008131115	Weight Vest 110-116	Class 1
008131116	Weight Vest 122-128	Class 1
008131117	Weight Vest 134-142	Class 1
008131118	Weight Vest 146-152	Class 1
008131119	Weight Vest X-Small	Class 1
008131120	Weight Vest Small	Class 1
008131121	Weight Vest Medium	Class 1
008131122	Weight Vest Large	Class 1
008131123	Weight Vest X-Large	Class 1
008131124	Weight Vest XX-Large	Class 1
008131010	Hygiene Cover Ecoverde® 150x200 cm	Class 1
008131011	Hygiene Cover Ecoverde® 140x200 cm	Class 1
008131012	Hygiene Cover Ecoverde® 110x125 cm	Class 1
008131013	Hygiene Cover Ecoverde® 100x140 cm	Class 1
008131140	Weight Duvet Futura 140x200 cm, 4 kg	Class 1
008131141	Weight Duvet Futura 140x200 cm, 6 kg	Class 1
008131142	Weight Duvet Futura 140x200 cm, 8 kg	Class 1
008131143	Weight Duvet Futura 140x200 cm, 10 kg	Class 1
008131144	Weight Duvet Futura 140x200 cm, 12 kg	Class 1
008131145	Weight Duvet Futura 140x200 cm, 14 kg	Class 1
008131180	Weight Duvet Nova 140x200 cm, 4 kg	Class 1
008131181	Weight Duvet Nova 140x200 cm, 6 kg	Class 1
008131182	Weight Duvet Nova 140x200 cm, 8 kg	Class 1
008131183	Weight Duvet Nova 140x200 cm, 10 kg	Class 1
008131184	Weight Duvet Nova 140x200 cm, 12 kg	Class 1
008131185	Weight Duvet Nova 140x200 cm, 14 kg	Class 1
008131186	Weight Duvet Nova 100x140 cm, 2.3 kg	Class 1
008131187	Weight Duvet Nova 100x140 cm, 3.7 kg	Class 1
008131188	Weight Duvet Nova 100x140 cm, 5.0 kg	Class 1