

Declaration of Conformity

(Försäkran om överensstämmelse)

Manufacturer **AKLA AB**
Parkgatan 15
SE-696 33 Askersund, Sweden

SRN **SE-MF-000004567**

First Aid products for wounds. Classification Class I, Rule 4 Annex VIII Regulation MDR 2017/745/EU

Bandages and dressings. Intended to be used as a mechanical barrier.

REF	Benämning	Product name	Basic UDI
REF: 69129	Rivbar kompress	Tearable dressing	7311410691296T
REF: 94355	Skallförband		73114109435574
REF: 95490	Påfyllningskassett	Plasterdispenser refill	7311410954907J
REF: 95492	Plåsterdispenser	Plasterdispenser	7311410954907J
REF: 97442	Näsförband	Nose bandage	7311410974367S
REF: 97435	Fingerkit	Fingerkit	7311410974367S
REF: 97436	Fingertub	Fingertube	7311410974367S

Swabs Intended to be used for cleansing of minor wounds

REF: 94408	Sårtvättare	Wound swab	7311410944086Y
Art.No: 94407	Sårtvättare , 10pack REF 94408	Wound swab	7311410944086Y
Art.No: 94410	Sårtvättare , 20pack REF 94408	Wound swab	7311410944086Y
Art.No: 94418	Sårtvättare , 40pack REF 94408	Wound swab	7311410944086Y

We hereby declare that the that the technical file of these devices comply with the General Safety and Performance Requirements of Annex I in the MDR 2017/745/EU.

Notified Body for our Quality System and higher risk classes:

ISO 13485:2016; Certificate number 0106644-01. Intertek Medical Notified Body AB, 0413

Askersund 2024-03-07
AKLA AB

Eva Janmark
Managing director