

Declaration of Conformity

(Försäkran om överensstämmelse)

Manufacturer **AKLA AB**
 (Enhagsslingan 2)
 Box 534
 SE-182 15 Danderyd, Sweden

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	7311410954927N
REF: 95495	Plåsterdispenser blue	Plasterdispenser, blue	7311410954957U
REF: 95499	Påfyllningskassett, blå	Plasterdispenser blue refill	73114109549984
REF: 97442	Näsförband	Nose bandage	7311410974367S
REF: 97435	Fingerkit	Fingerkit	7311410974357Q

Swabs Intended to be used for cleansing of minor wounds

REF: 94408	Sårsväddare	Wound swab	7311410944086Y
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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 0106644-00. Intertek Medical Notified Body AB, 0413

Täby 2021-05-17
AKLA AB



Eva Janmark
Managing director