

**AKLA AB**

Enhagslingan 2, SE-187 40 Täby  
Sweden

14 March 2024

**Notified Body Confirmation Letter**

**Reference: MDD Cert No. 41314724-02 - CN00257-01**

To whom it may concern,

**Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices**

This letter confirms that, Intertek Medical Notified Body AB, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2862 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

**AKLA AB**

Enhagslingan 2, SE-187 40 Täby  
Sweden  
SRN Number: SE-MF-000004567

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,



---

Brian Mather  
Certification Manager  
Intertek Medical Notified Body AB

**Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
See appendix			

**Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification

**Confirmation Letter Revision History**

Date	NB internal reference traceable to each version of the letter	Action

<b>Device Name</b>	<b>MDR Device classification</b>	<b>Substitute for MDD device [N/A if identical]</b>	<b>MDD Certificate Reference(s) of the devices, and the NB Identification</b>
Första Förband First Aid bandage 7,5x12 cm	I(s)	N/A	41310145, NB0143
Första Förband First Aid bandage 17x17cm	I(s)	N/A	41310145, NB0143
Trauma 4 Första Förband Multi Försvar First Aid bandage 20 x 20 cm	I(s)	N/A	41310145, NB0143
Trauma 2 Första Förband Försvar First Aid bandage 17 x 17 cm	I(s)	N/A	41310145, NB0143
Trauma 2 Första Förband Försvar First Aid bandage 20 x 26 cm	I(s)	N/A	41310145, NB0143
Första Förband First Aid bandage 20x20cm	I(s)	N/A	41310145, NB0143
Första Förband First Aid bandage 20x20 cm	I(s)	N/A	41310145, NB0143
Trauma 3 Första Förband kombi/Tryck Försvar First Aid bandage 20 x 20 cm	I(s)	N/A	41310145, NB0143
Kompress nonwoven Dressing nonwoven 5 x 7,5 cm	I(s)	N/A	41310145, NB0143
Burngel dressing 30x40 cm	IIb	N/A	41314724, NB0143
Burngel 3,5 gram	IIa	N/A	41314724, NB0143
Burngel dressing 5x5 cm	IIb	N/A	41314724, NB0143
Burngel dressing 10x10 cm	IIb	N/A	41314724, NB0143
Burngel dressing 20x20cm	IIb	N/A	41314724, NB0143
Burngel dressing 30x30 cm	IIb	N/A	41314724, NB0143
Burngel dressing 40x60cm	IIb	N/A	41314724, NB0143
Burngel dressing 100x100cm	IIb	N/A	41314724, NB0143
Burngel dressing 100x200 cm	IIb	N/A	41314724, NB0143
Burngel 50ml	IIa	N/A	41314724, NB0143
Burngel 100ml	IIa	N/A	41314724, NB0143
Trauma 1 Kompress nonwoven Dressing nonwoven 5 x 7,5 cm	I(s)	N/A	41310145, NB0143
Trauma 5 Frimis I, Kompress nonwoven Dressing nonwoven 20 x 30 cm	I(s)	N/A	41310145, NB0143
Trauma 6 Frimis II, Kompress nonwoven Dressing nonwoven 30 x 50 cm	I(s)	N/A	41310145, NB0143
Burngel dressing 10x40 cm	IIb	N/A	41314724, NB0143
Burngel dressing 20x45 cm	IIb	N/A	41314724, NB0143
Burngel dressing 30x40 cm	IIb	N/A	41314724, NB0143
Burngel 3,5 gram	IIa	N/A	41314724, NB0143
Burngel dressing 5x5 cm	IIb	N/A	41314724, NB0143
Burngel dressing 10x10 cm	IIb	N/A	41314724, NB0143
Burngel dressing 5x15cm	IIb	N/A	41314724, NB0143

<b>Device Name</b>	<b>MDR Device classification</b>	<b>Substitute for MDD device [N/A if identical]</b>	<b>MDD Certificate Reference(s) of the devices, and the NB Identification</b>
Burngel dressing 20x20cm	IIb	N/A	41314724, NB0143
Burngel dressing 30x30 cm	IIb	N/A	41314724, NB0143
Burngel dressing 40x60cm	IIb	N/A	41314724, NB0143
Burngel dressing 100x100cm	IIb	N/A	41314724, NB0143
Burngel dressing 100x200 cm	IIb	N/A	41314724, NB0143
Burngel 59ml	IIa	N/A	41314724, NB0143
Burngel 118 ml	IIa	N/A	41314724, NB0143
Tvättare sår, sterile water	I(s)	N/A	41310145, NB0143
Trachealkompress nonwoven Dressing Tracheal 7,5 x 10 cm	I(s)	N/A	41310145, NB0143
Näsförband	I(s)	N/A	41310145, NB0143