

Language: English

## EU DECLARATION OF CONFORMITY

1. No DCS/1236722442-A (unique identification of the product)

2. Manufacturer:

Apto Enterprises

Mughal Pura Murad Pur Road, Sialkot – 51310, Pakistan

3. Designated Authorized Representative:

Mak Web

Korte putstraat 1F  
5211KP  
'S-Hertogenbosch  
Netherlands

4. This declaration of conformity is issued under the sole responsibility of the manufacturer (or installer): Lucas Mak van Waay – Mak Web

5. Object of the declaration (identification of product allowing traceability. It may include a color image of sufficient clarity to enable the identification of the product, where appropriate.)

DCS/1236722442-A - Novaex verpleegkundige scharensset (Color coated)



6. The object of declaration described in point 4 is in conformity with the relevant Union harmonisation legislation:

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Yes, MDR 2017/745 for Class 1 Medical Devices.

7. References to the relevant harmonized standards used, or references to the specifications in relation to which conformity is declared:

Yes, ISO13485:2016 and ISO7741:1986

8. Where applicable: the notified body ... (Dynamex Certification Services APTO05243659)... performed ... CE certificate of conformity ... and issued the certificate:

The EUT described above has been tested by Dynamex Certification Services with the listed standards and found in compliance with all relevant EU Directive. It is possible to use CE marking to demonstrate the compliance with the EU Directive.

The certificate applies to the tested sample above mentioned only and shall not imply an assessment of the whole production. It is only valid with test report number APTO05243659

9. Additional information:

Signed for and on behalf of: Novaex a brand of Mak Web

Korte putstraat 1F – 5211KP 'S-Hertogenbosch – The Netherlands

Lucas Mak van Waay – Owner Mak Web (Importer)

A handwritten signature in blue ink, consisting of a large, stylized 'L' followed by several horizontal strokes and a long, sweeping underline.