



STATEMENT

regarding instructions for use

ZARYS International Group sp. z o.o. sp.k. hereby declares that the low-risk medical device listed below, which is well established on the market, can be safely used without instructions for use. In this regard, we inform you that according to Annex I of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, Chapter II, point 13.1 the instructions for use will not be supplied with the device:

Name of the medical device:

duoNEX, dicoNEX, docNEX

sterile syringes for single use

types: **2-part luer; 3-part luer; 3-part luer lock; 3-part catheter; 3-part amber luer-lock**

catalogue number: 002ML-2CZ-B to 100ML-3CZ-CEW-BL

Classification: medical device of Class IIa Rule 2 according to Annex IX of the Council Directive 93/42/EEC.

Place and date of issue:

Zabrze, 14.05.2021

Signed on behalf of the Manufacturer:

PRODUCT MANAGER
ZARYS International Group sp. z o.o. sp.k.

A handwritten signature in blue ink, appearing to read "Zofia Rogala".

Zofia Rogala