



## 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:

sterile surgical suction cannulas

type: Yankauer; ball tip; sump tip; Poole type; Pinpoint type; Duckbill type

version: with suction control; without suction control

catalogue number: KO-00104 to KO-00214

Classification: medical device of Class IIa Rule 7 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.

  
Zofia Rogala