„Manufacturer's-Declaration – Preliminary Products“

Implementation of the Regulation EU 2017-745“

With this manufacturer's declaration we confirm that we - W.R. Lang GmbH, Hafenstr. 83, D-56564 Neuwied – have implemented the product-related requirements regarding:

1) Quality Management according to DIN EN ISO 13485
2) Risk Management according Annex I Regulation EU 2017/745
3) Compliance with the essential requirements Annex I Regulation EU 2017/45
4) Stability and Material Conformity
5) Biocompatibility or alternative evidence of physiological safety
6) Function and safety when combining the following materials
7) Regular clinical follow-up observation

This manufacturer's declaration applies to the following products:

a) LaNe® leather articles ArtNr. 3208X
b) upper- lining- and covering leathers ArtNr. 34XXX und 35XXX
c) sleek leather ArtNr. 36016 – 36020 und 36042 - 36043
d) orthopaedic leathers ArtNr. 33059 - 33066
e) insole leather ArtNr. 3312X
f) hook-and-loop tapes, elastic band, webbing belt strap ArtNr. 64400 – 64601 and 43266 – 43267 and 43275 – 43278
g) LaNe® elastik-covering cork ArtNr. 8040X
h) padding materials, lining- und covering materials ArtNr. 84XXX
i) EVA-sheets and –wedges ArtNr. 22XXX and 22XXXX
j) SANDWICH® OT sheets ArtNr. 8590X
k) prefabricated insoles ArtNr. 2-...
l) milling/CAD CAM materials ArtNr. 902XX und 1-... und 3-... und 4-... und 5-... und 6-...
m) LaNe® Combi-Sheets ArtNr. 84189-84424 – 84646-84495
n) custom-made fabrications ArtNr. Consisting of a combination of letters and numbers

Please, note the information on exceptions and exclusions for use on the article labels and the shipping documents.

The above mentioned products can be used for the manufacture of class I medical devices.

The declaration is valid until 31.12.2023.

Neuwied, 18.06.21

(Laura Lang)

(Martin Lang)