

DECLARATION ACC (EC) 2017/745 (MDR), ARTICEL 22

SET-0004-00

We

Lohmann & Rauscher International GmbH & Co. KG

Westerwaldstraße 4

56579 Rengsdorf

Germany

hereby declare that for the following products

Product group/name

Rosidal sys

Ref(s):

16984, 190008

Basic UDI-DI

4021447-SET0004-ZV

we verified the mutual compatibility of the devices and, if applicable other products, in accordance with the manufacturers' instructions and have carried out the activities in accordance with those instructions

we packaged the system or procedure pack and supplied relevant information to users incorporating the information to be supplied by the manufacturers of the devices or other products which have been put together

the activity of combining devices and, if applicable, other products as a system or procedure pack was subject to appropriate methods of internal monitoring, verification and validation

Place, Date

Lohmann & Rauscher International GmbH & Co. KG

ppa. Oliver Opitz, Management Representative

Record 24.09.2020