

EC DECLARATION OF CONFORMITY

Date of issue: 03.04.2023

Conformity declaration issued by:

The Legal and Actual Manufacturer	Schroder Medikal Ticaret Anonim Şirketi
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E-mail	info@schroderhealth.de
Brand	Schröder:
Products	SDC 1180, Metal Cabinet
Description and function designation:	Using at hospitals including all applicable accessories.
Classification of the product as the medical device:	Class I nonsterile, without measuring function

A) Declaration

We declare that the said products are safe under the conditions of common use in compliance with the instructions and that measures have been taken to ensure the conformity of all the products brought to market with basic requirements of directives related thereto, stated in paragraph B.

B) Fulfilled technical requirements

These products' characteristics comply with the technical parameters related to it and stated in MDR 2017/745 as amended, which stipulates the technical parameters for healthcare products.

C) Means of assessing conformity

Conformity was assessed by the procedure stated MDR(EU) 2017/745- Medical Device Regulation $\,$

D) Used standards

The said products fulfill the requirements of these harmonized technical standards which were used for assessing of conformity: -EN60601-2-41:2009, -EN 60601-1-2:2015, -EN 60601-1:2006 +A1:2013, -TS EN 60601-1, -EN 60601-2-52:2010

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