

EC CERTIFICATE
Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

No. 5-810-200-1611

National Institute of Pharmacy and Nutrition
Directorate of Device Testing and Clinical Engineering (EMKI)

certifies that the manufacturer:

Sanatmetal Ortopédiai és Traumatológiai Eszközök Gyártó Kft.
3300 Eger, Faiskola u. 5.
Hungary

for the products / product category:

WIWE cardiac diagnostic device family

applies a quality system which meets the requirements of Directive 93/42/EEC concerning medical devices, Annex II.

Registry number of the related audit report: **42-5905-2016**

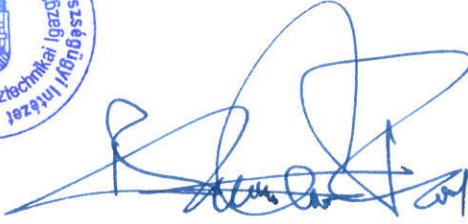
This certificate is valid until **2021-11-13** supposed that the results of the regular yearly surveillance audits are satisfactory.

Issued by EMKI as a Notified Body with identification number **1011**.

Budapest, 2016-11-14


Deputy General Director




Head of EMKI



EMKI 1585

The authenticity and validity of the certificate are verifiable at EMKI.