Manufacturer:

EMED SP. Z O. O. SP. K.

ul Ryżowa 69A

05-816 Opacz-Kolonia

NIP. 5271996617

Concerning: **Change of the Notified Body CE 1011→ CE 2274.**

Devices of classes IIa and IIb.

Dear Sir/Madam,

On 21 April 2020, the new Notified Body, i.e. TUV NORD Polska Sp. z o.o., with the identification number **CE 2274** took over the tasks of surveillance over EMED products marked with the identification number of the previous Notified Body, i.e.. The surveillance exercised by the new Notified Body covers devices of Classes IIa and IIb and is valid for products listed in Annex 1 to the CE certificate No. TNP_MDD_0320_4919_2020.

All the devices which had been placed on the market and put into service until 21 April 2020 still continue to meet the requirements of regulations and harmonised standards consistent with Directive 93/42/EEC concerning medical devices and they may be safely used as intended.

The previous notified body gave the company EMED its consent to the placing on the market of products with a label and/or instructions for use bearing the identification number of the previous Notified Body (CE 1011) until 20 October 2023.

In light of the above, there will be probable and allowable situations where products of the company EMED and their accompanying documentation will be marked with the identification numbers of both Notified Bodies.

Sincerely yours,

Wioletta Nurczyk

Quality Manager

emed SP. Z O. O. SP. K.
05-816 Opacz Kolonia, ul. Ryżowa 69A
NIP 527-199-66-17 Regon: 010949914
Nr KRS: 0000407548
tel. (22) 723 08 00, fax. (22) 723 00 81
e-mail: emed@emed.pl