# To Whom It May Concern

Subject: New Medical Device Regulation (MDR) effective from 26th of May 2021

Products concerned:

- SHIELDskin CHEM™ NEO NITRILE™ 300
- SHIELDskin™ ORANGE NITRILE™ 260/300
- ecoSHIELD™ Eco Nitrile PF 250
- ecoSHIELD™ Eco Latex PF 250
- duoSHIELD™ LPS Latex 240
- duoSHIELD™ PFT Latex 240
- duoSHIELD™ PFT Nitrile 240
- duoSHIELD™ ICE NITRILE™ 240
- SMARTLine™ Powder-free blue nitrile gloves, 240

Date: May 18th 2021

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Dear Sir/Madam

On 26th May 2021, the EU Medical Device Regulation (EU) 2017/745 (MDR) will come into force, thereby replacing the Medical Device Directive (MDD) 93/42/EEC. We are pleased to advise that all our laboratory (boxed) gloves comply with the MDR. In terms of the MDR, our laboratory (boxed) gloves are medical examination gloves and as such are considered Class 1 medical devices.

Of specific note are the following:

SRN

According to Article 31 of MDR (EU) 2017/745, a Single Registration Number (SRN) needs to be obtained. The SRN identifies the manufacturer and as per Annex IV of the MDR needs to feature on all applicable Declarations of Conformity, where the MDR is referenced. With the central European medical database, EUDAMED, not operational until May 2022, the SRN is provided by the local EU competent authority. In the case of SHIELD Scientific, the SRN has been provided by CIBG Farmatec in the Netherlands. For your information, our SRN is **NL-MF-00000169.**

UDI

In an effort to enforce better traceability of medical devices, the EU through the MDR is implementing a Unique Device Identification (UDI) system. The latter consists of three parts: Basic UDI-DI, UDI-DI and UDI-PI. At this stage, SHIELD Scientific has fulfilled its obligations in terms of having available a Basic UDI-DI. The latter is the main key in EUDAMED for linking devices with relevant technical documentation and you will notice that the Basic UDI-DI is already displayed on relevant DOCs. The Basic UDI-DI is generated by an approved EU body (in the case of SHIELD Scientific this is GS1) and more information on this subject (plus UDI generally) can be found on this very helpful website: https://easymedicaldevice.com/udi/#entities

In due course, both the UDI-DI (Device identifier) and UDI-PI (Product identifier) will appear on the packaging (UDI-carrier), but it should be noted that according to Article 123(3f) of the MDR for class 1 medical devices this is not mandatory until May 2025. The UDI-DI is static and identifies the product (e.g. duoSHIELD™ ICE NITRILE™ 240), whilst the UDI-PI is dynamic in so far as it covers lot number, expiry date etc.

Whilst all our laboratory (boxed) gloves comply with the MDR, please note that SHIELDskin™ ORANGE NITRILE™ 300 Sterile and the SHIELDskin XTREME™ range of sterile and non-sterile cleanroom gloves are not registered as medical devices. In common with all SHIELD Scientific gloves, SHIELDskin™ ORANGE NITRILE™ 300 Sterile and the SHIELDskin XTREME™ range of sterile and non-sterile cleanroom gloves are registered as Category III (Complex Design) according to the EU Personal Protective Equipment Regulation (EU) 2016/425 (PPER).

Should you have any further questions on the manufacturing of SHIELD Scientific gloves, please do not hesitate to contact your SHIELD Scientific representative.

Trusting to have informed you sufficiently.

SHIELD Scientific B.V.

J.F. Robles
General Manager