DECLARATION OF CONFORMITY

Hereby the manufacturer H + H Medical Devices GbR represented by its Managing Director and Safety Representative Mr. Andreas Hellwig declares that the products with references

10.300, 10.300F, 10.301, 10.303 and 10.310 and the registered trade name

OneStep® Cleargel

are manufactured under sole responsibility of the manufacturer in accordance with the conditions set out in EU guideline MDR 2017/745/EU for medical products. The products mentioned above are classified as Class I products. Classification was determined in accordance with the rules set out in Annex VIII of the guideline, rule 1.

The products are used for better conductivity in electrophysiological examinations. This is achieved with containing electrolytes and results in better signal transmission.

The SRN number for our company is: DE-MF-000009442

The base UDI-DI is 426050343CG003QA

Münster, 24.04.2024

Andreas Hellwig
Graduate Biologist

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