

EU Declaration of Conformity

Personal Protective Equipment:

Name:	Dermatril® 740 Size 9
Item Code:	074009081C
Type:	Hand & Arm Protection - Gloves
Manufacturer:	KCL GMBH Am Kreuzacker 9, Industriepark Rhor

Am Kreuzacker 9, Industriepark Rhon 36124 Eichenzell GERMANY

This declaration of conformity is issued under the sole responsibility of the manufacturer:

KCL GMBH

The object of the declaration described above is in conformity with:

• the relevant Union harmonization legislation: Personal Protective Equipment Regulation (EU) 2016/425

The fulfilment of the applicable essential health and safety requirements set out in Annex II has been demonstrated.

the relevant harmonised standard(s) and/or technical specification(s): EN 420:2003+A1:2009, EN ISO 374-5:2016, EN ISO 374-1:2016

The notified body:

CTC Number: 0075

Performed the EU type-examination and issued the EU type-examination certificate number: 0075/1445/162/11/18/2756 issued 27/11/2018.

The object of the declaration described above is in conformity with:

- the relevant Union harmonization legislation: Medical Devices Regulation (EU) 2017/745, Annex VIII: Class I
- the relevant harmonised standard(s) and/or technical specification(s): EN 455-1:2022, EN 455-2:2015, EN 455-3:2015, EN 455-4: 2009, EU-declaration of conformity based on annex II and III
- document number: BASIC UDI DI: 40081987401789750DV KCL GMBH SRN DE-MF-000005184.

The PPE is subject to the conformity to type assessment procedure based on quality assurance of the production process (Module D) set out in the legislation: Personal Protective Equipment Regulation (EU) 2016/425

Under the surveillance of the notified body:

TÜV Rheinland LGA Products GmbH Number: 0197

Notified Body performed the Module D and issued the document number: EP 60 159880 0001 dated 02/11/2021.

Signed for and on behalf of:KCPlace of issue:EicDate of issue:31Name:MaFunction:Qu

KCL GMBH Eichenzell 31/01/2023 Markus Weber Quality Manager

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