# IVD Technical File Declaration of Conformity for LumiraDx CRP (S-RA-TEC-0018)

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| Document Number: | S-RA-REP -00356 | Revision: | 1 |

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# EC Declaration of Conformity for LumiraDx CRP (EN)

**We, the legal manufacturer, as stated below herby declares under our sole responsibility,**

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|---|---|
| **Legal Manufacturer:** | LumiraDx UK Ltd. |
| **Address:** | Dumyat Business Park<br>Alloa FK10 2PB<br>United Kingdom |
| **EC Authorized Representative:** | LumiraDx AB<br>Västra Vägen 5A<br>169 61 Solna<br>Sweden |

**that the identified product to which this declaration relates,**

| **Identification** | |
|---|---|
| **Product Name** | LumiraDx CRP |
| **Catalogue Numbers** | L004000101024 L004000101048<br>L004000102024 L004000102048<br>L004000103024 L004000103048<br>L004000104024 L004000104048<br>L004000105024 L004000105048<br>L004000106024 L004000106048<br>L004000107024 L004000107048<br>L004000108024 L004000108048<br>L004000110024 L004000110048<br>L004000111024 L004000111048 |
| **GMDN Code** | 58768 - C-reactive protein (CRP) IVD, kit, fluorescent immunoassay |
| **Classification** | General IVD |
| **Conformity Assessment Route** | Annex III (excluding Section 6) of 98/79/EC |

**is in conformity with the following European Regulations and Directives as transposed into the national laws of the member states:**

| **Directives and Regulations** |
|---|
| Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices |

**Signed for and on the behalf of Manufacturer LumiraDx UK Limited:**

| Name | David Scott | Position: | Chief Technology Officer |
|---|---|---|---|
| Signature | | Date: | |
|  | | 10 January 2022 | |

**With approval of this Declaration of Conformity, we hereby affix the CE Mark to the product.**