



## EC Declaration of Conformity

**Manufacturer Name:** Metrex Research, LLC  
**Business Address:** 28210 Wick Road, Romulus, MI, 48174, USA

**Device Category:** Medical Device Disinfection Wipe

**Classification:** IIa per Annex IX, Rule 15

**Technical File:** CaviWipes

**GMDN Code and Term:** 58077 (Medical Device Disinfection Wipe)

**Product Tradename(s):** CaviWipes, Kavo Wipes

**CE Authorized Representative:** Kerr Italia S.r.l., Via Passanti 332, I-84018 Scafati, (SA), Italy

**Harmonized Standards Applied:** EN ISO 13485, EN ISO 14971, EN 1041, EN ISO 15223-1, EN ISO 10993-1, EN 62366, BS EN 13727, EN 13624, EN 16615, EN 14885, EN 13697, EN 14476

**Other Standards Applied:** ISTA 3E-17, ASTM E2362, ASTM E1053

**Declaration Statement:**

*We hereby declare that the product line(s) listed above and part numbers detailed in the attached Product List conform to the relevant provisions of the CE Council Directive 93/42/EEC dated 14 June 1993 as amended by 2007/47/EC in accordance with Annex V, section 3.2 Conformity Assessment Procedure as demonstrated by the CE certificate No 02118, issued by BSI (British Standard Institution), Notified Body No 2797.*

**Regulatory Affairs Signature:**

5/20/2019

Issue Date

Name: Jennifer Evans

Title: Senior Director, Regulatory Affairs



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Product List	
REF	Description
4731160	European CaviWipes 160 Count 12/CS
4731160-1	European CaviWipes 160 Count 12/CS
4731065	European CaviWipes XL 65 Count 12/CS
4731245	European CaviWipes Flat Pack 45 Count 20/CS
13-1350	Kavo Wipes 65 Count 12/CS