DECLARATION OF CONFORMITY

4bases SA
Stabile Suglio – Via Cantonale 18, 6928 Manno – Switzerland (CH)
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4bases SA declares that the products in tab. n°1

TAB. N°1

TARGET ENRICHEMENT		
codice	**descrizione**	**N°test**
1-0011-1-16	KRAS NGS IVD KIT exons 2,3,4	16
1-0061-1-16	NRAS NGS IVD KIT exons 2,3,4	16
1-0020-1-16	BRAF NGS IVD KIT exon 15	16
1-0030-1-16	EGFR NGS IVD KIT exons 18,19,20,21	16
1-1000-1-16	KRAS/NRAS IVD KIT	16
1-1100-1-16	KRAS/NRAS/BRAF IVD KIT	16
1-0122-1-16	BENKit Multi Cancer IVD panel	16
PRG-HR1-01	HR1 (Breast - Ovary) NGS KIT	16

Validated with the instrument system

Applied Biosystems® GeneAmp® PCR System 9700
(Applied Biosystems®)

e / and

ProFlex™ PCR System
(Applied Biosystems®)

e / and

Ion PGM™ Sequencer system
(Life Technologies Corporation)

is designed and manufactured at its own head office:

4BASES SA
Stabile Suglio – Via Cantonale 18, 6928 Manno – Switzerland (CH)

Meets the provisions of the Directive 98/79/EC of 27 October 1998 on In Vitro Diagnostic Medical Devices, and the "Essential Requirements" of Annex I.

4BASES SA has a full quality assurance system conform to the European regulatory standard EN ISO 13485, that has been certified by the notified body **Kiwa Cermet Italy S.p.A.**