KONFORMITÄTSERKLÄRUNG / DECLARATION DE CONFORMITE
DECLARATION OF CONFORMITY / DICHIARAZIONE DI CONFORMITA

Name und Adresse der Firma Nom et adresse de l'entreprise Nome e indirizzo della ditta Name and address of the firm	BEIJING STEELLEX SCIENTIFIC INSTRUMENT COMPANY 1 Fourth Street 25 Road (E) Shangdi Information Industrial Base, Beijing, China, 100085.

Wir erklären in alleiniger Verantwortung, dass / Nous déclarons sous notre propre responsabilité que /Dichiariamo sotto nostra responsabilità che / We declare under our sole responsibility that

	PT Liquid Kit, PT Lyophilized Kit APTT Kit, FIB Liquid Kit, FIB Lyophilized Kit, TT Liquid Kit, TT Lyophilized Kit , NCP, ANCP
das Medizinprodukt le dispositif médical the medical device il dispositivo medico	Automated Coagulation Analyzer(M600L,M600H), Semi-automated Coagulation Analyzer(LG-Paber-I, LG-Paber), Full Automated Biochemistry Analyzer(FR1, FR400), ESR, RBC Deformation and Aggregation Analyzer Bezeichnung, Typ oder Modell, Chargen- oder Seriennummer, ev. Herkunft und Stückzahl Nom, type ou modèle, numéro de lot ou série, év. source et nombre d'exemplaires Nome, tipo o modello, numero di lotto o di serie, ev. fonte e numero di esemplari/Name, type or model, batch or serial number, possibly sources and number of items
der Klasse / de la classe / della classe / of class	Professional-testing device according to IVDD Nach Richtlinie 98/79/EG / selon directive 98/79//CE /secondo direttiva 98/79/CE / according to direct. 98/79/EC.

allen Anforderungen der Medizinprodukte-Richtlinie 98/79/EG entspricht, die anwendbar sind/ remplit toutes les exigences de la directive sur les dispositifs médicaux 98/79/CE) qui le concernent / soddisfa tutte le disposizioni della direttiva 98/79/CE che lo riguardano /meets all the provisions of the directive 98/79/EC which apply to it.

	EN 375:2001 Information supplied by the manufacturer with in vitro diagnostic reagent for professional use
Angewandte harmonisierte Normen, nationale Normen oder andere normative Dokumente Normes harmonisées, normes nationales et autres documents normatifs appliqués Norme armonizzate o nazionali applicate,altri documenti normativi applicati Applied harmonised standards, national standards or other normative documents	EN 980: 2003 Graphical symbols for use in the labeling of medical devices EN 13612: 2002 Performance evaluation of in vitro diagnostic medical devices EN 13640: 2002 Stability testing of in vitro diagnostic medical device EN13641: 2002 Elimination or reduction of risk of infection related to in vitriol diagnostic reagent EN 13975:2003 Sampling procedures used for acceptance testing of in vitro diagnostic medical devices-Statistical aspects En ISO 14971:2000 Risk analysis
Konformitätsbewertungsverfahren Procédure d'évaluation de la conformité Procedimento di valutazione della conformità Conformity assessment procedure	MDD 98/79/EC, Annex III

Beijing 2008-3-13

General Manager
Digitally signed by Efremova Iulia
Date: 2019.11.20 15:50:09 EET
Reason: MoldSign Signature
Location: Moldova

Ort, Datum / Lieu, date / Luogo, data / Place, date

Name und Funktion / Nom et fonction /Nome e funzione / Name and function