Align Technology Earns ISO 9001 Certification

Santa Clara, Calif. - October 19, 2001 -- Align Technology, Inc. (Nasdaq: ALGN), the inventor of the Invisalign® System, a proprietary method of straightening teeth without unsightly wires and brackets, announced today that it has received official certification as an ISO 9001 compliant manufacturer for both its Santa Clara, California and Lahore, Pakistan facilities. Certificates for ISO 9001, EN 46001 and ISO 13485 were awarded by TÜV Product Service, an independent auditor recognized as the worldwide leader in medical device certification.

ISO 9001 certification is awarded to organizations that have been audited and successfully maintain a compliant quality system, including product design. The EN 46001 / ISO 13485 standards document the more stringent European/International quality system requirements for medical device manufacturers.

"This certification supports our global expansion and marketing efforts," said Zia Chishti, chairman and Chief Executive Officer. "Doctors and consumers worldwide will recognize that this endorsement assures them the highest standards of quality control. Furthermore, the internal dedication to meet such rigorous standards while becoming one of the world's largest custom medical device manufacturers is impressive for a young company experiencing rapid growth and demonstrates our commitment to our customers," added Chishti.

About Align Technology

Align Technology designs, manufactures and markets the Invisalign System, a proprietary new method for treating malocclusion, or the misalignment of teeth. The Invisalign System corrects malocclusion using a series of clear, nearly invisible, removable appliances that gently move teeth to a desired final position. Because it does not rely on the use of metal or ceramic brackets and wires, the Invisalign System significantly reduces the aesthetic and other limitations associated with braces. Invisalign is appropriate for treating adults and older teens. Align Technology was founded in March 1997 and received FDA clearance to market the Invisalign System in 1998.

About TÜV Product Service

TÜV Product Service is a division of TÜV America Inc., headquartered in Danvers, MA, employing over 240 professionals throughout North America. As the leading European Union Notified Body for the Medical Devices, Active Implantable Medical Devices and In Vitro Diagnostic Directives, TÜV Product Service provides full suites of services for medical device manufactures which including ISO 9000, ISO 13485/88, EN 46000, FDA 510(k) reviews, CE Marking assistance, electromagnetic compatibility (EMC) testing and many additional global conformity assessment services.

This release may contain forward-looking statements based on Align Technology's current expectations. Forward-looking statements in this release include, without limitation, references to ISO certification and its impact on potential future sales and global expansion. These forward-looking statements involve risks and uncertainties. A number of important factors could cause actual results to differ materially from those in the forward-looking statements. A number of other factors that could cause actual results to differ materially, are discussed in more detail in Align Technology's Annual Report on Form 10-K, as well as other reports and documents filed from time to time with the Securities and Exchange Commission.